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(54) **DELIVERY CATHETER HANDLE AND METHODS OF USE**

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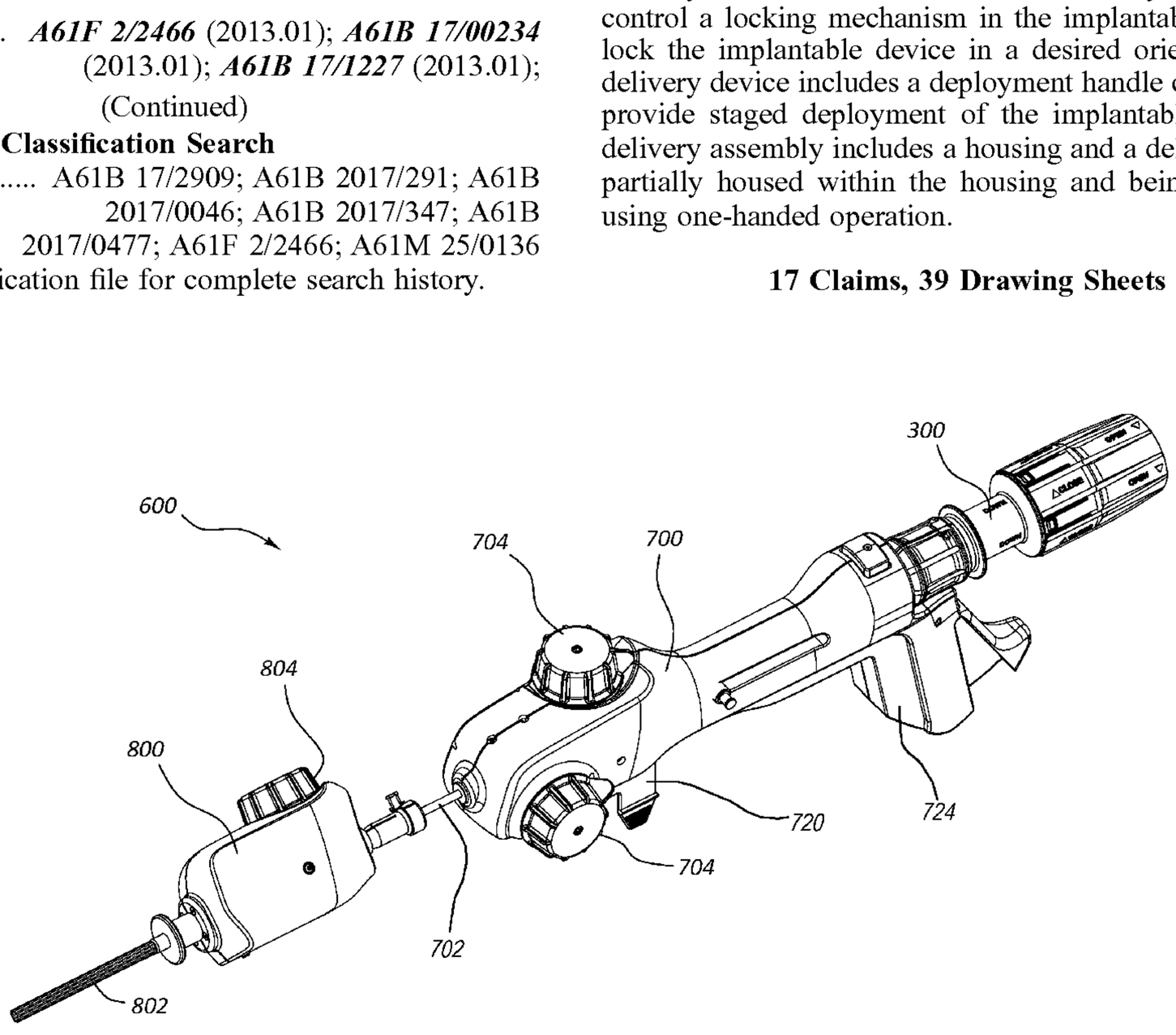
(57) **ABSTRACT**

Methods, devices, and systems are provided for performing endovascular repair of atrioventricular and other cardiac valves in the heart. A delivery device for delivering an implantable device to a target area includes a fluid management system for directing fluid and delivery device components to the target area. The delivery device includes a grip line assembly configured to control a gripper in the implantable device for grasping tissue at the target area. The delivery device includes a lock line assembly configured to control a locking mechanism in the implantable device to lock the implantable device in a desired orientation. The delivery device includes a deployment handle configured to provide staged deployment of the implantable device. A delivery assembly includes a housing and a delivery device partially housed within the housing and being adjustable using one-handed operation.

17 Claims, 39 Drawing Sheets



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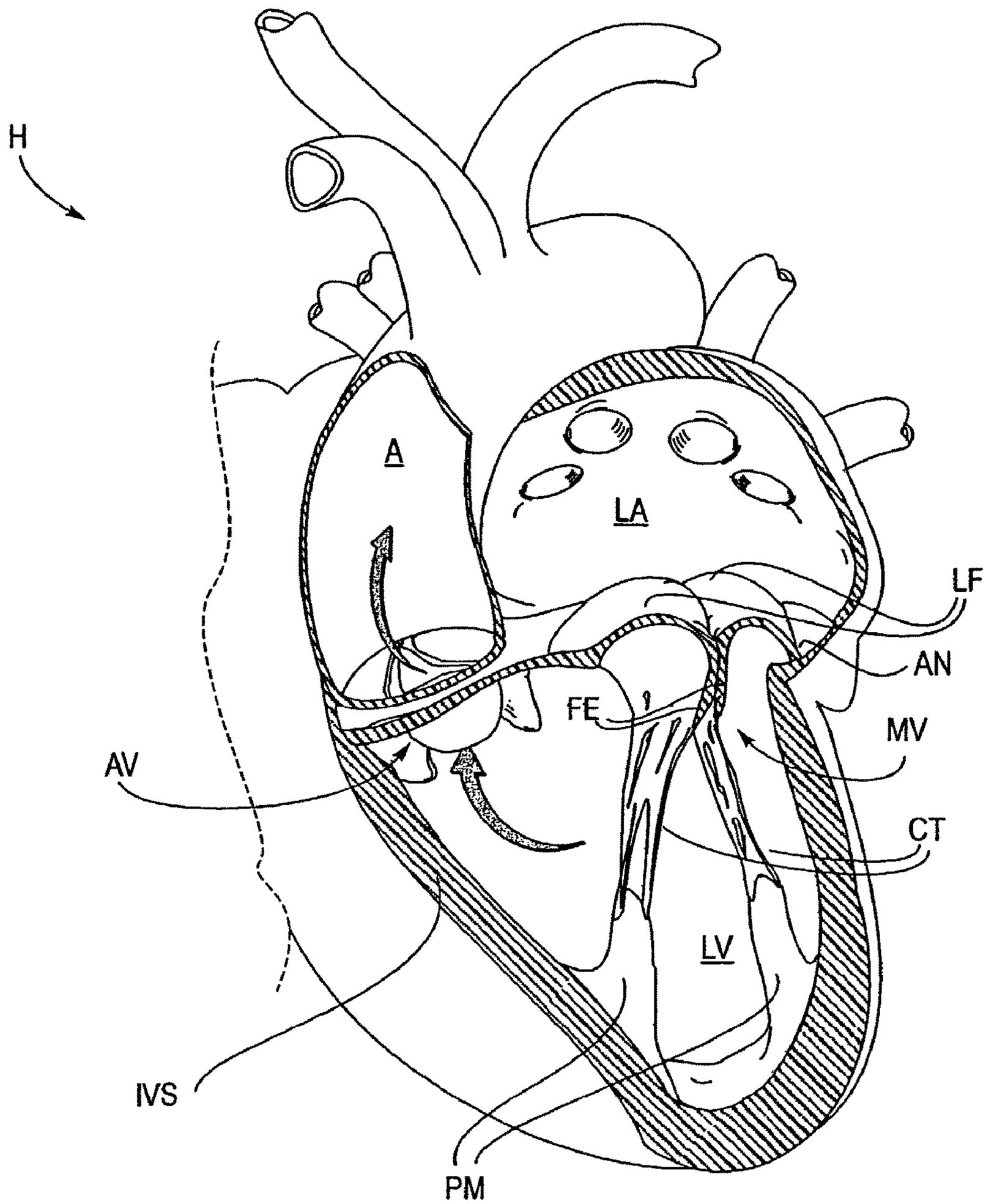

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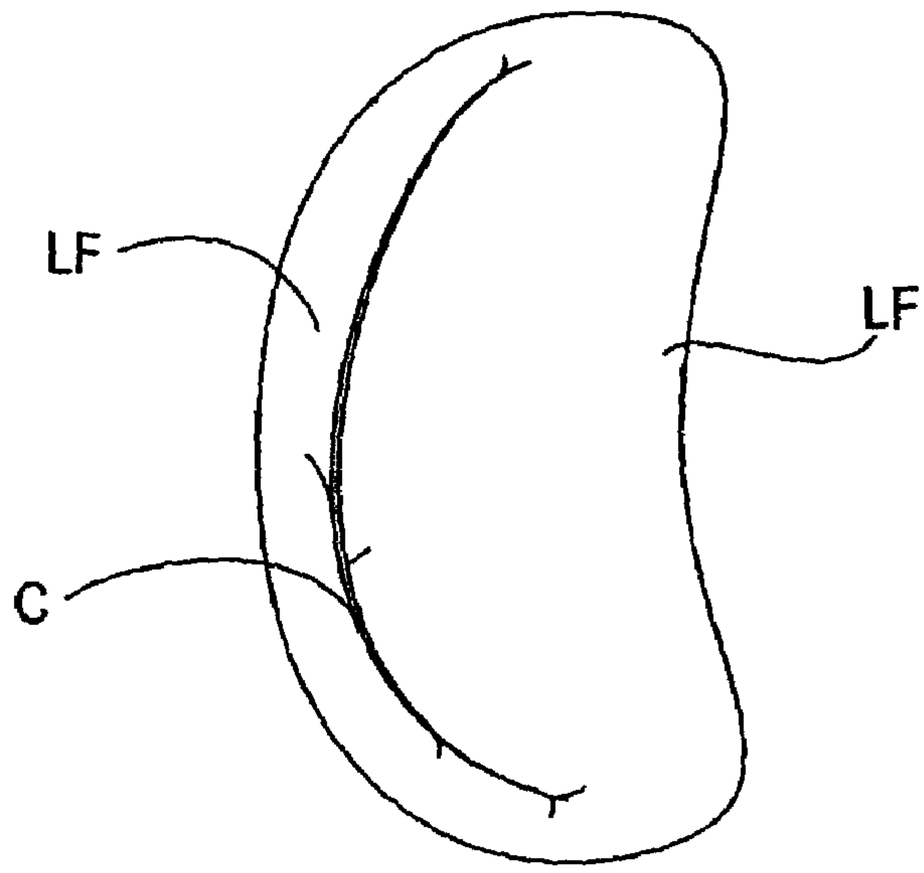

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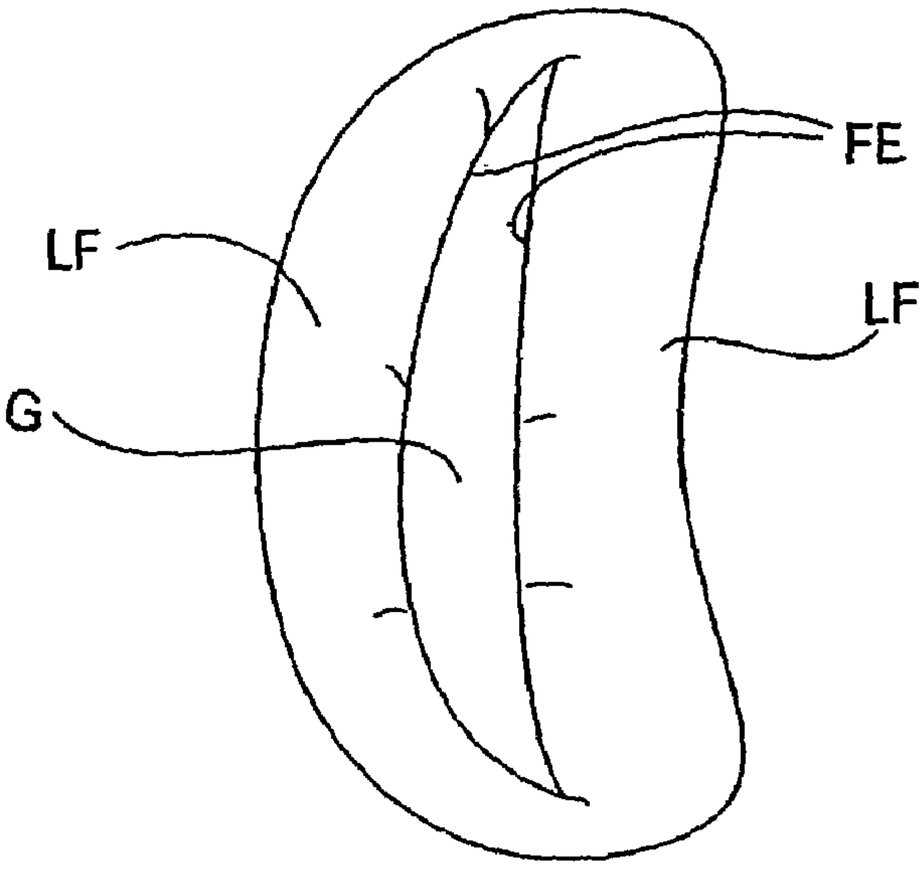

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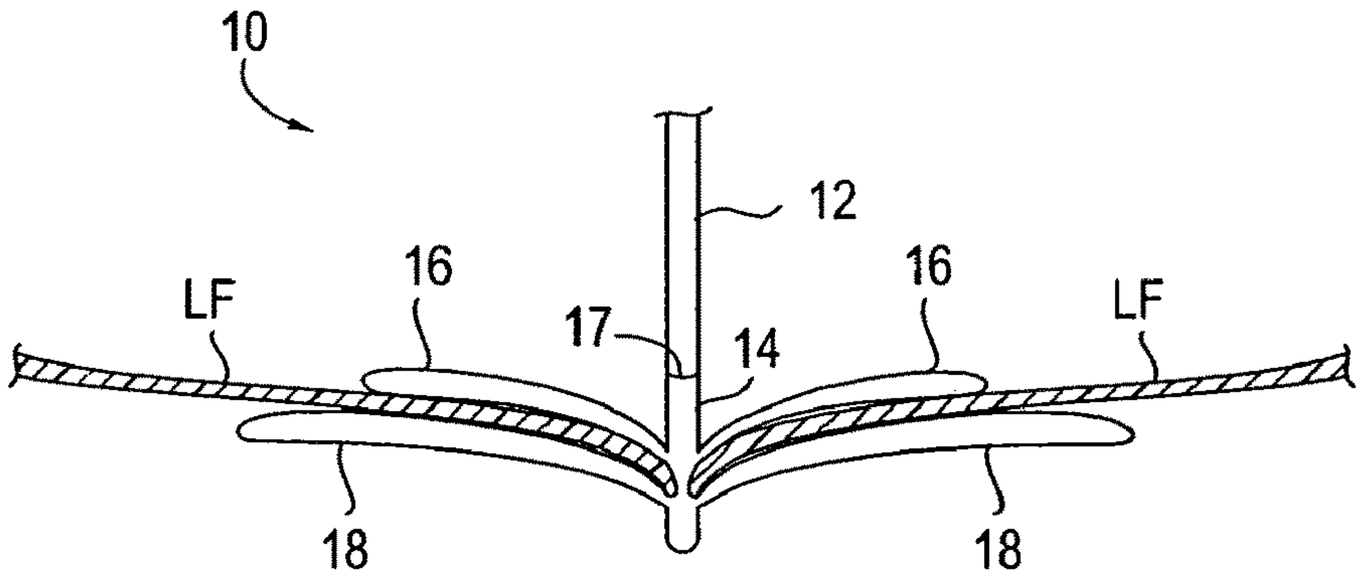

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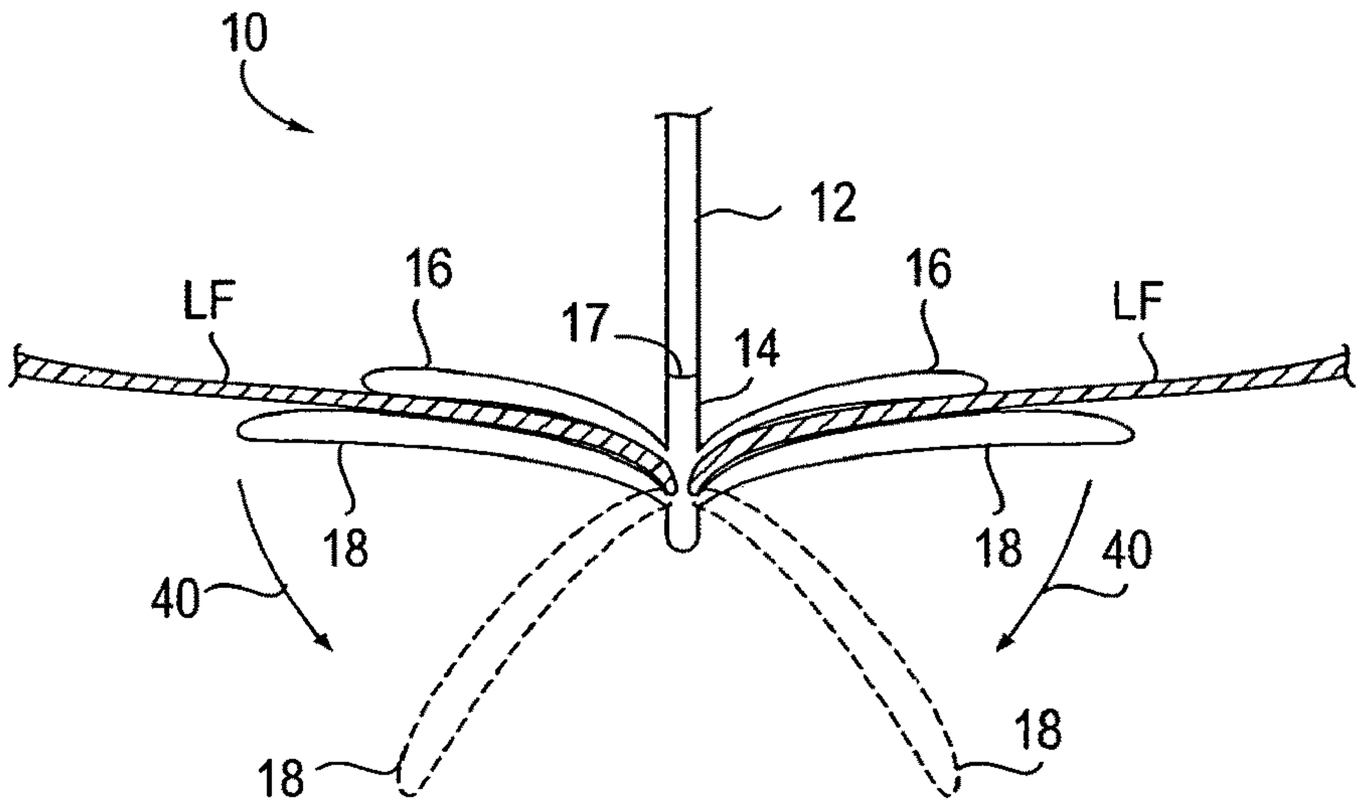

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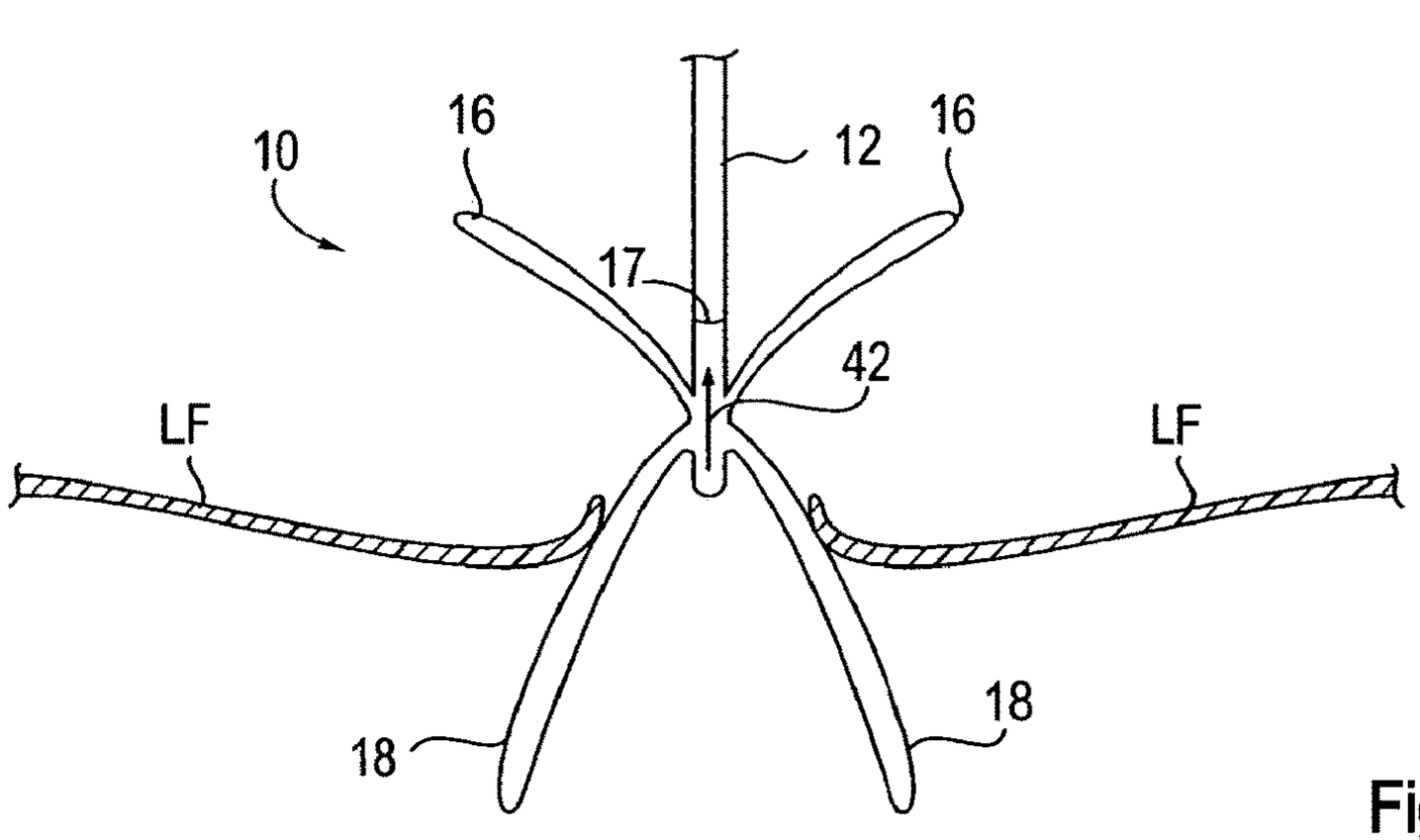

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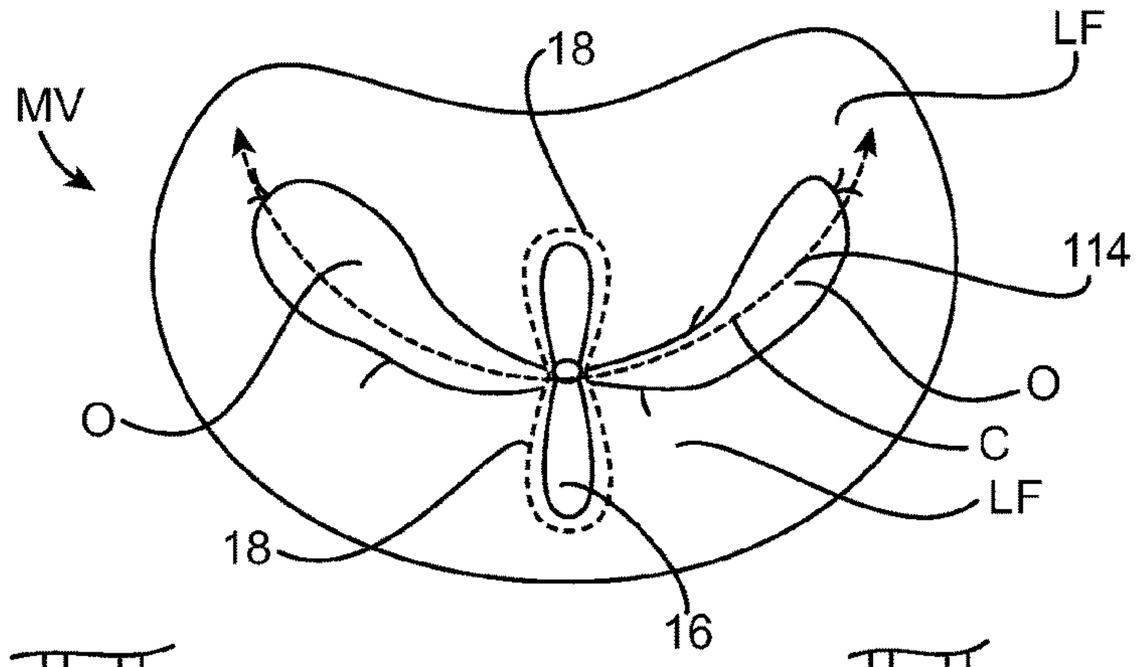

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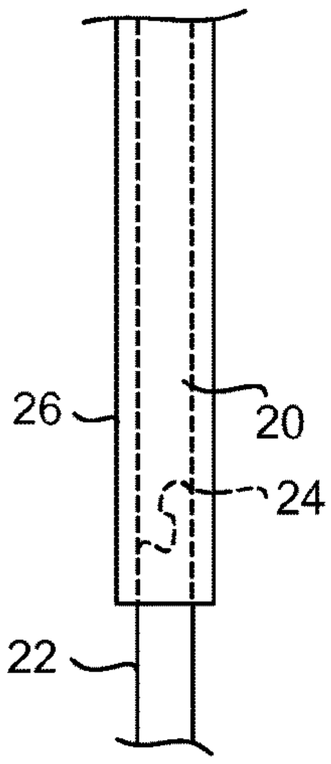

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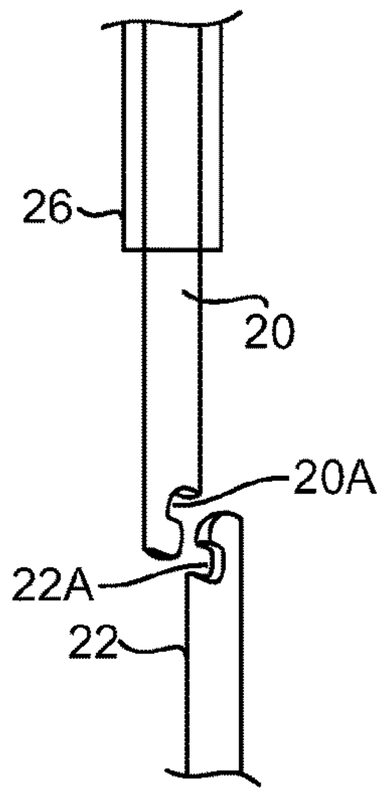

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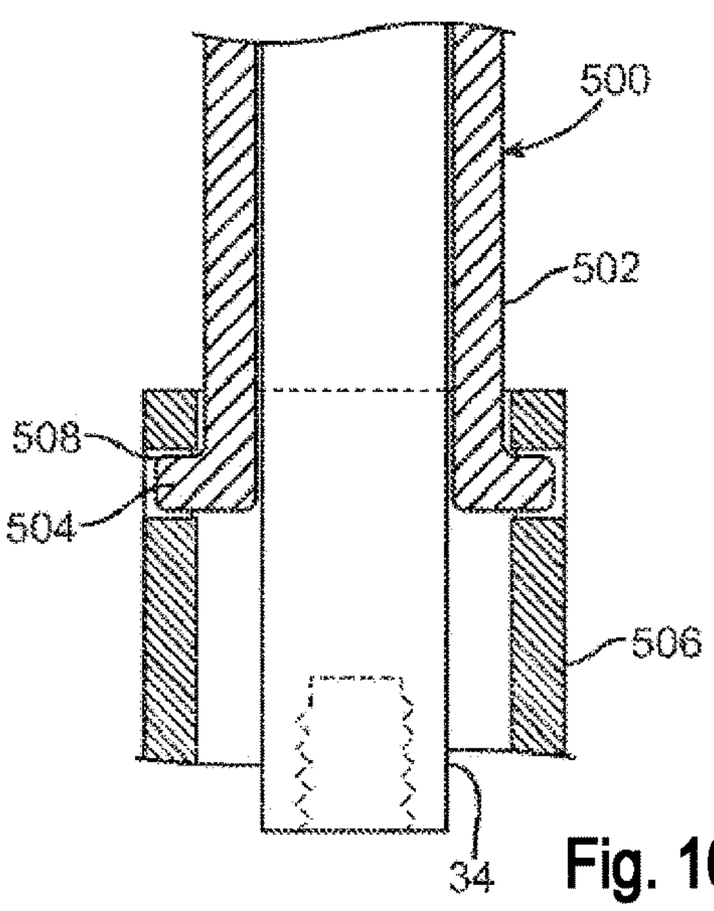

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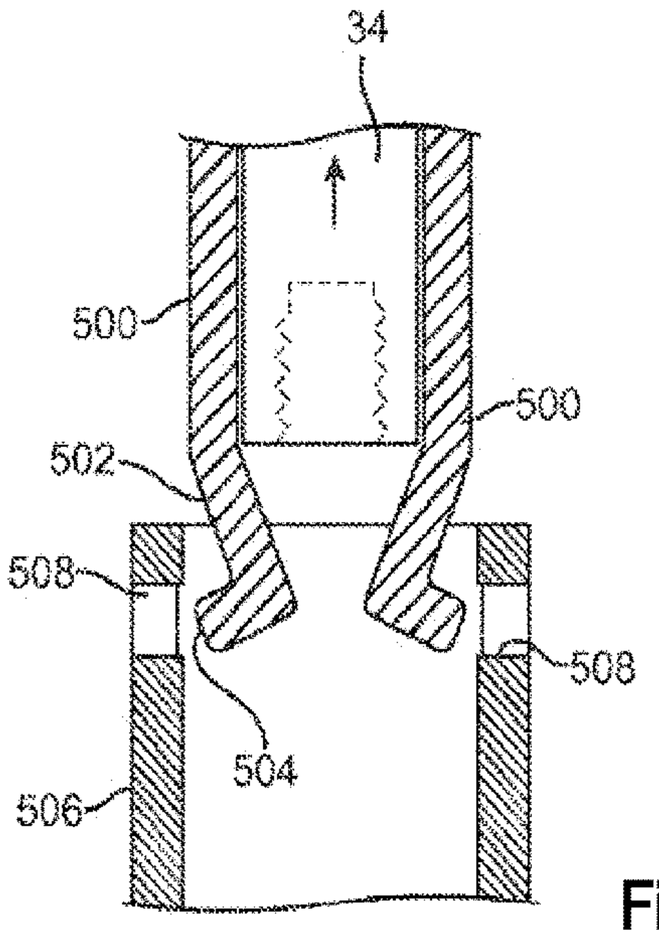

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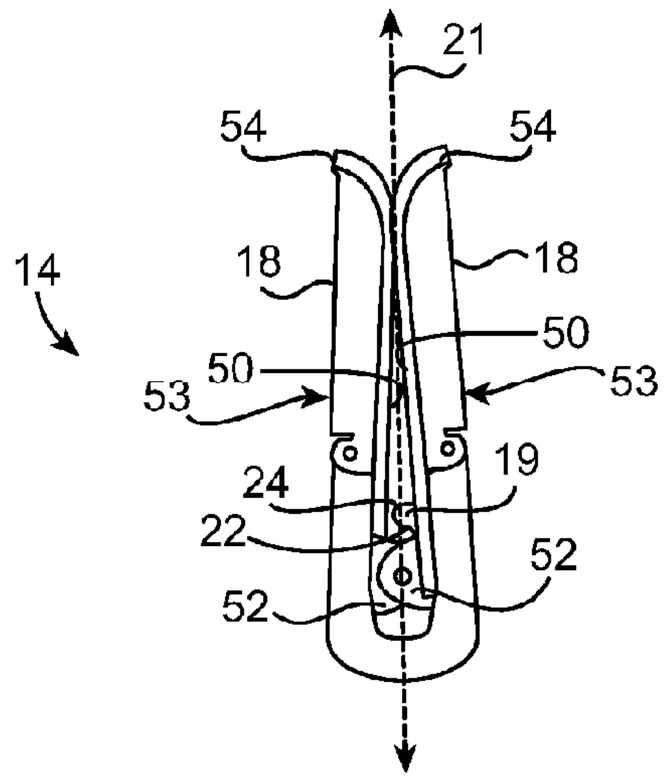

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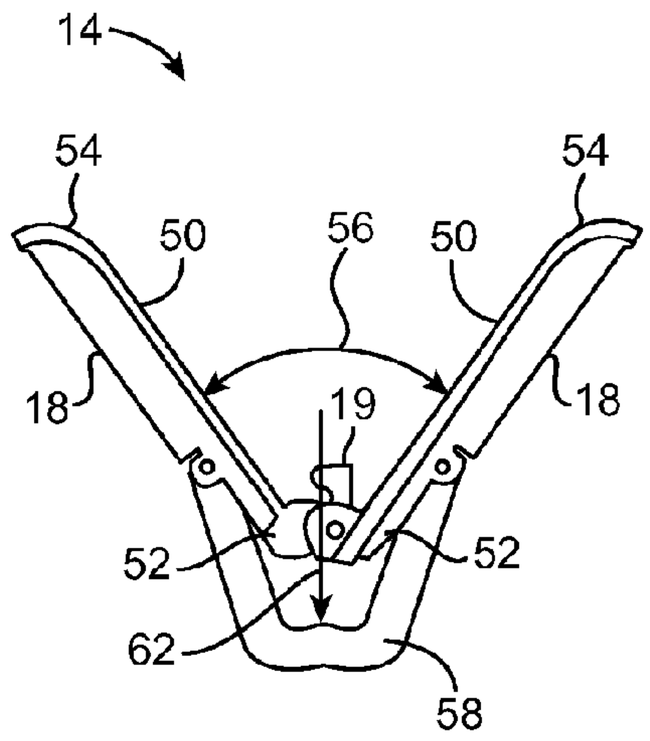

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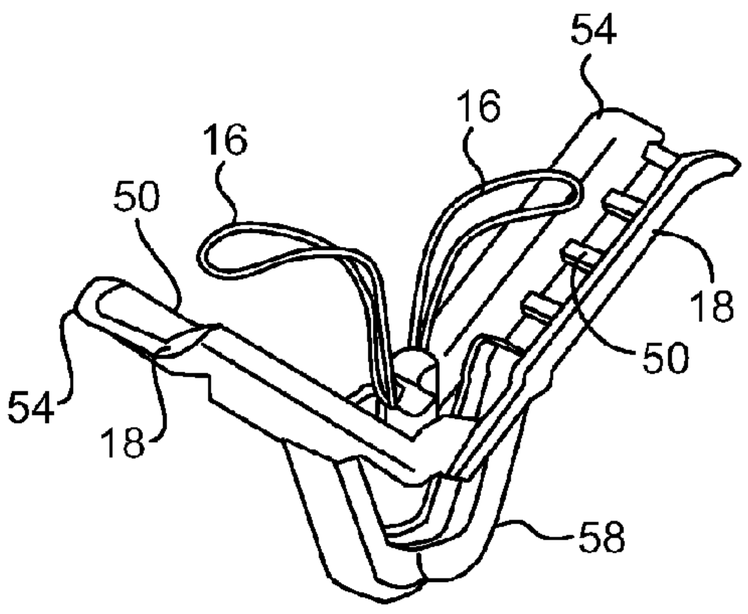

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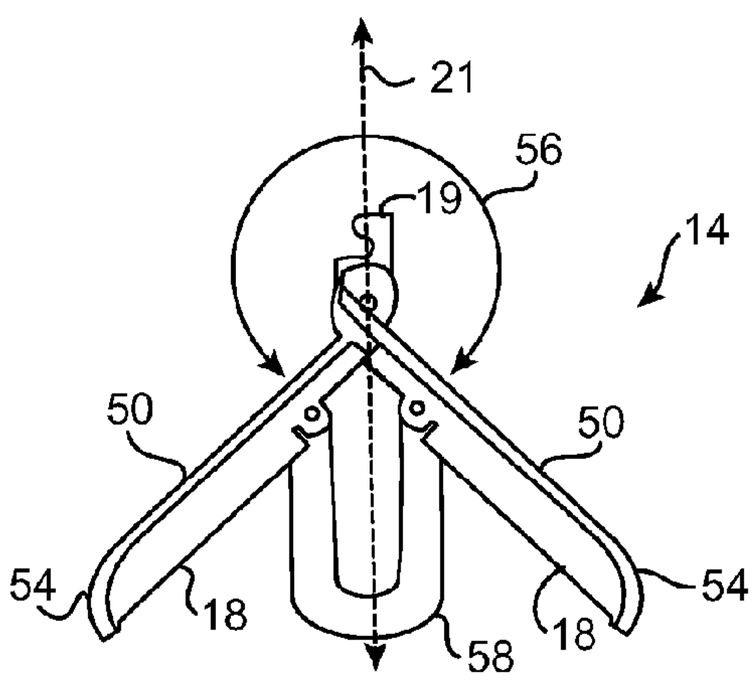

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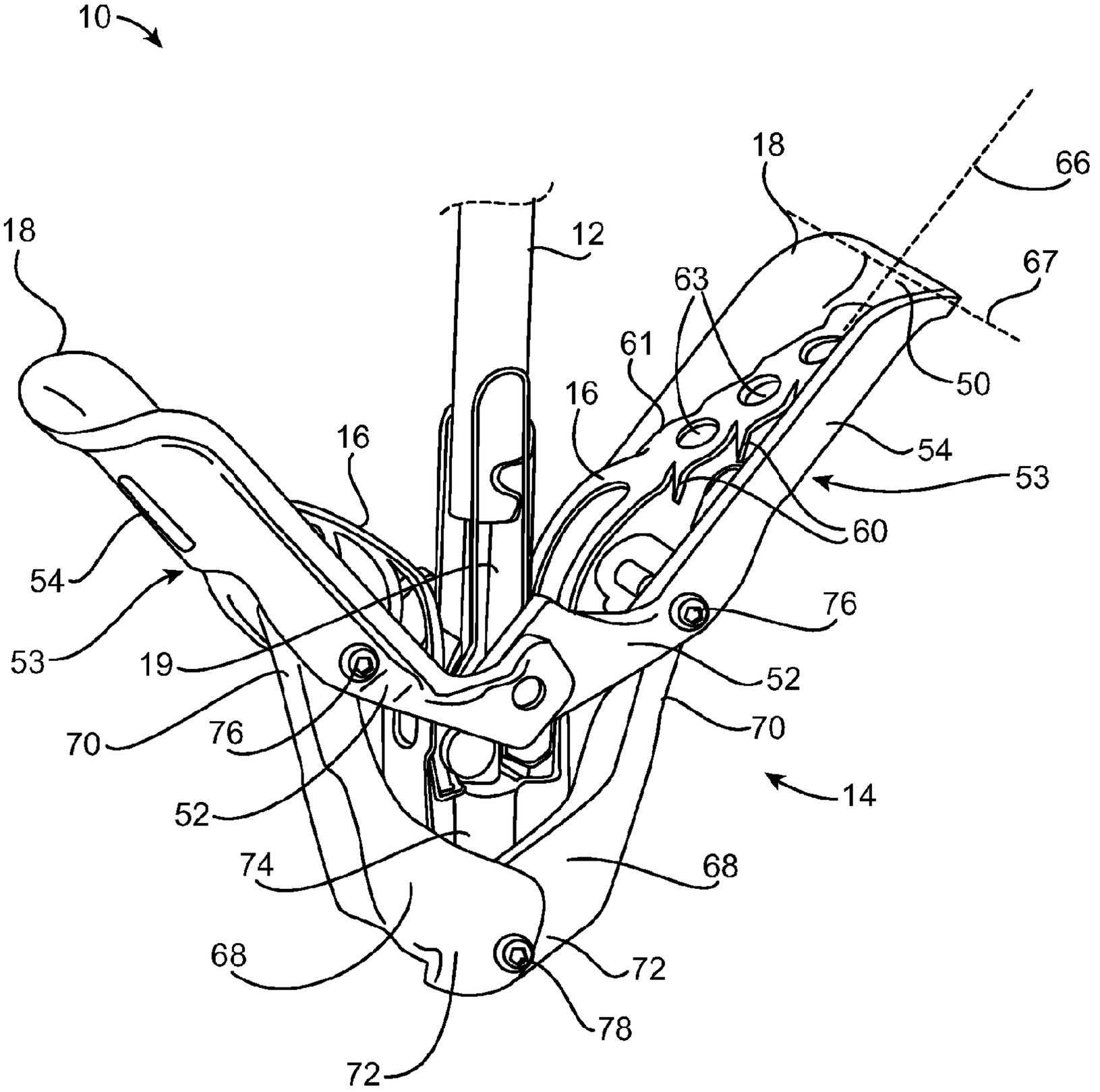
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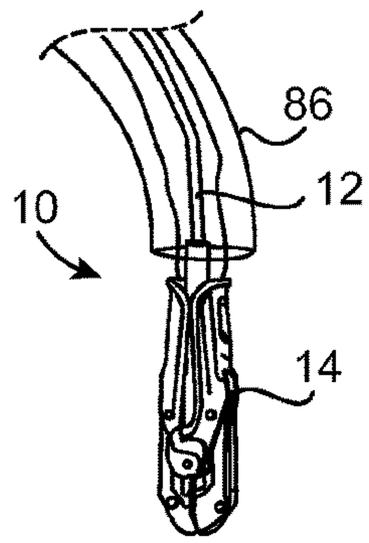
Fig. 16



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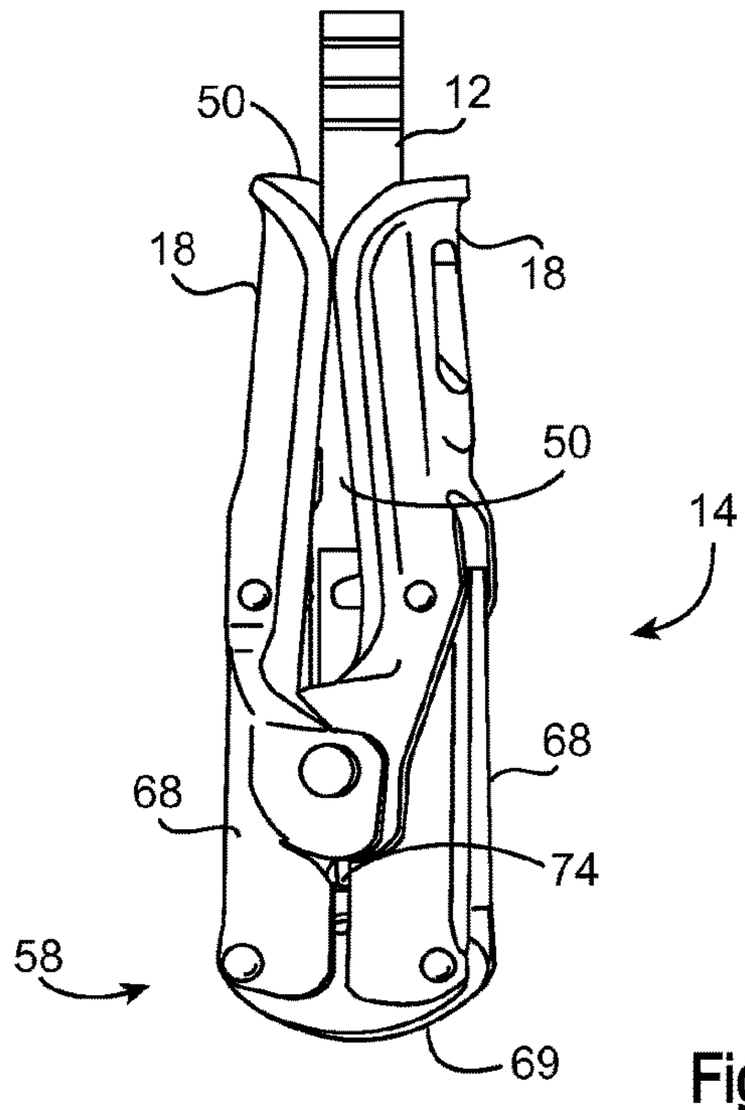

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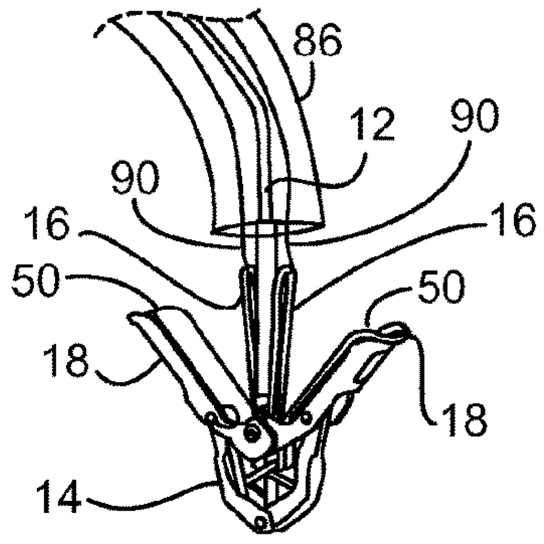

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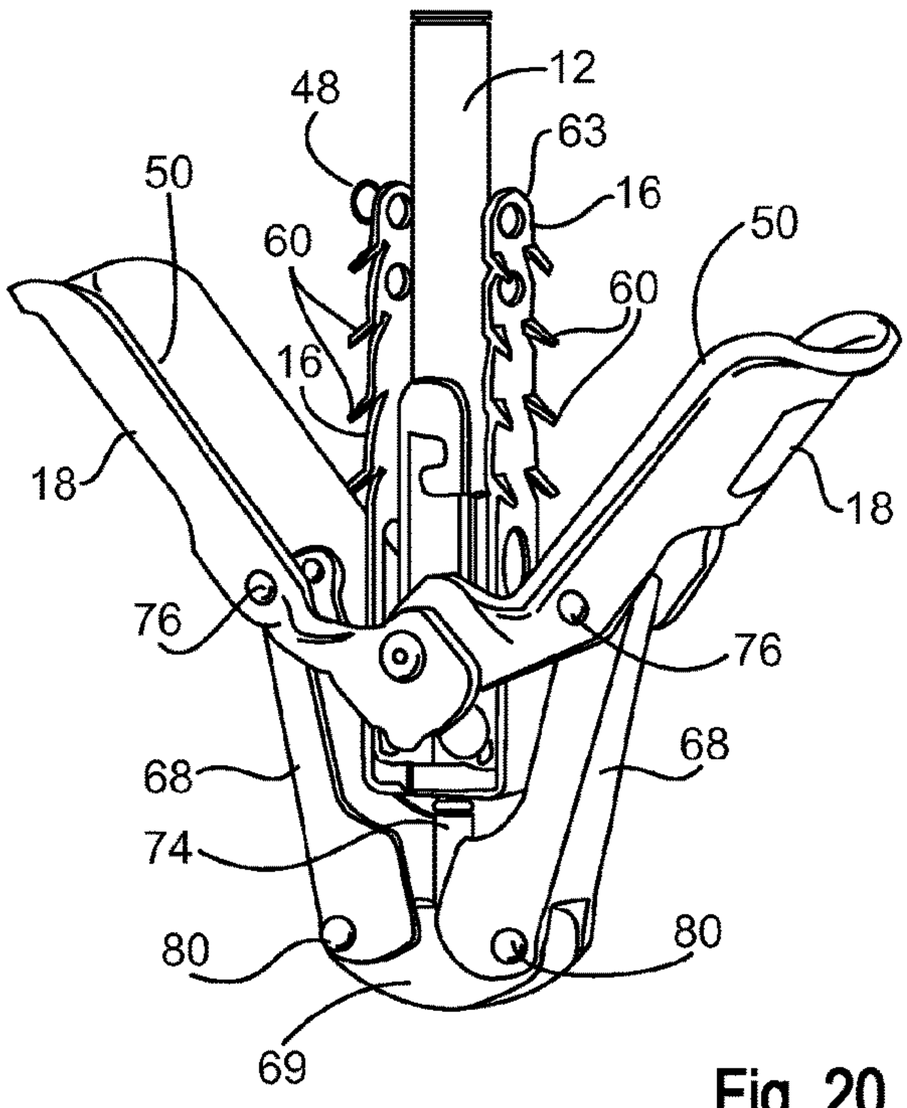

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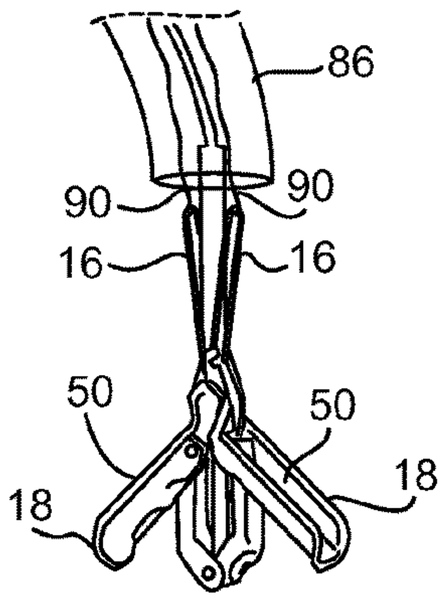

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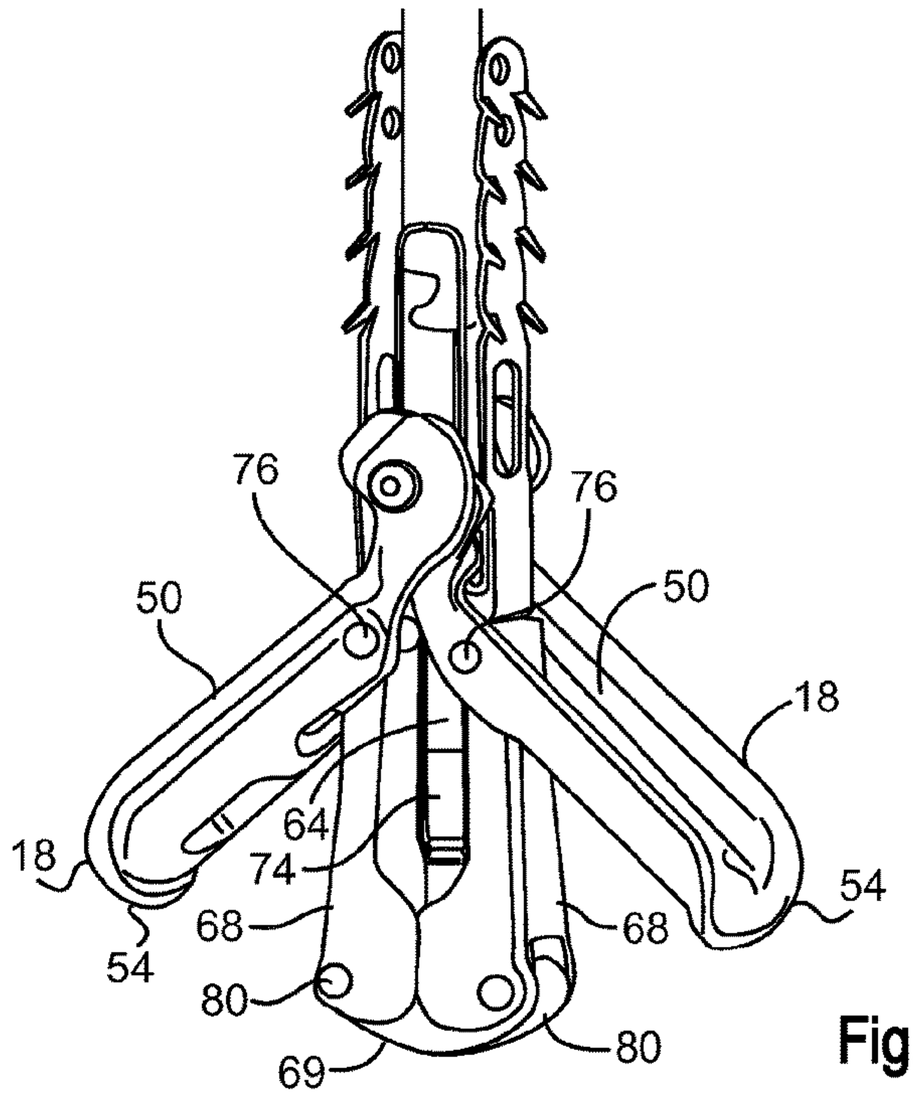

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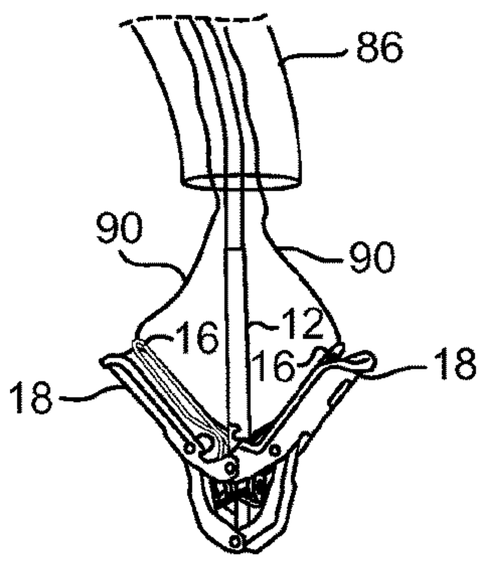

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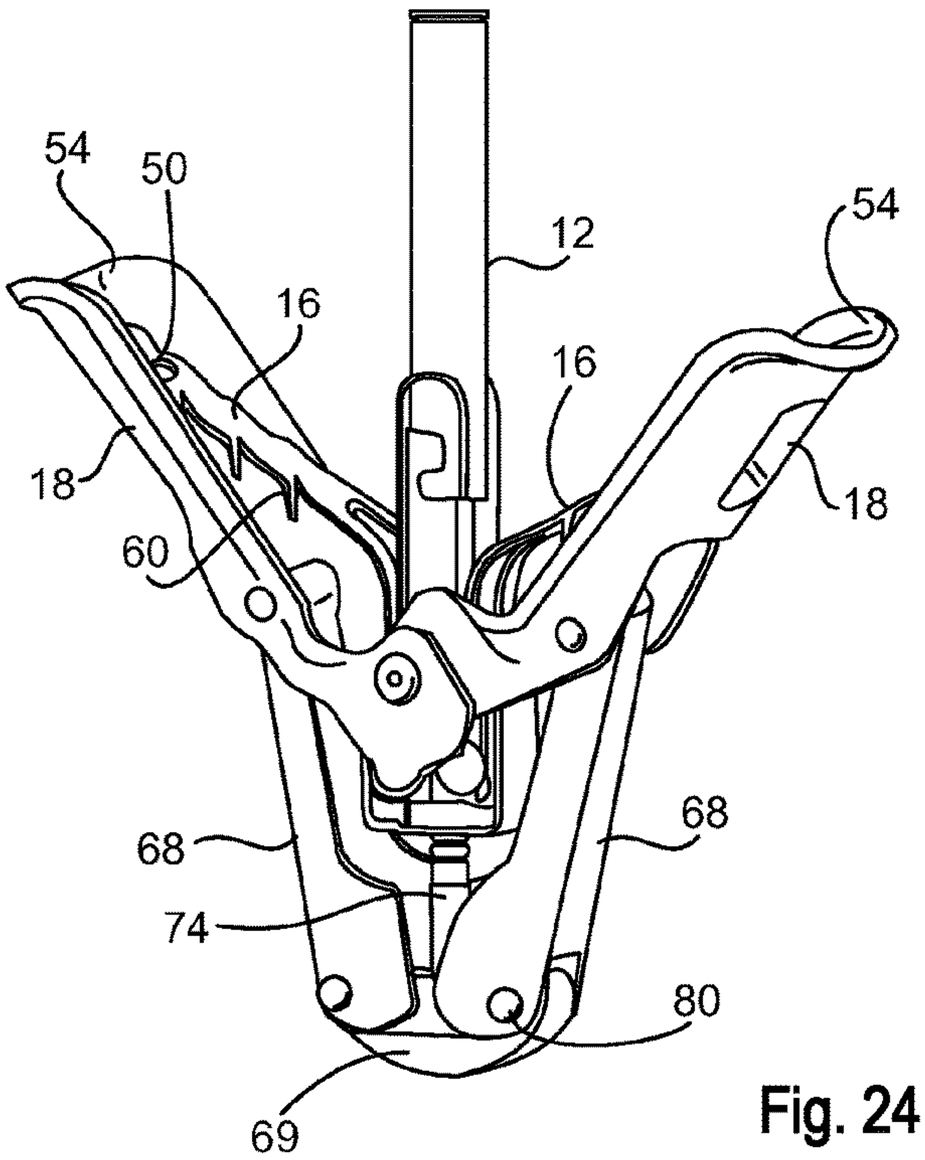

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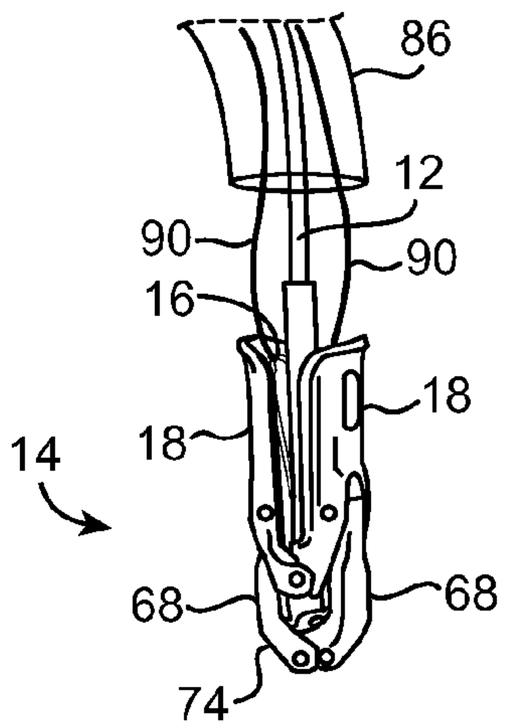

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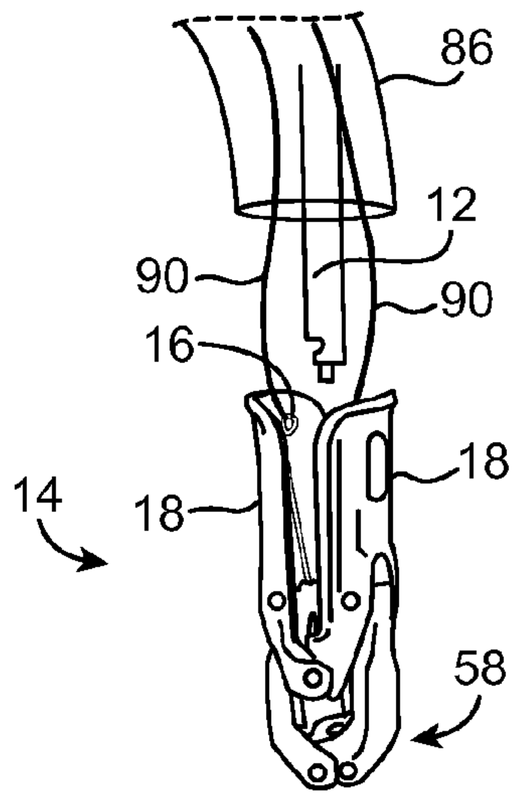

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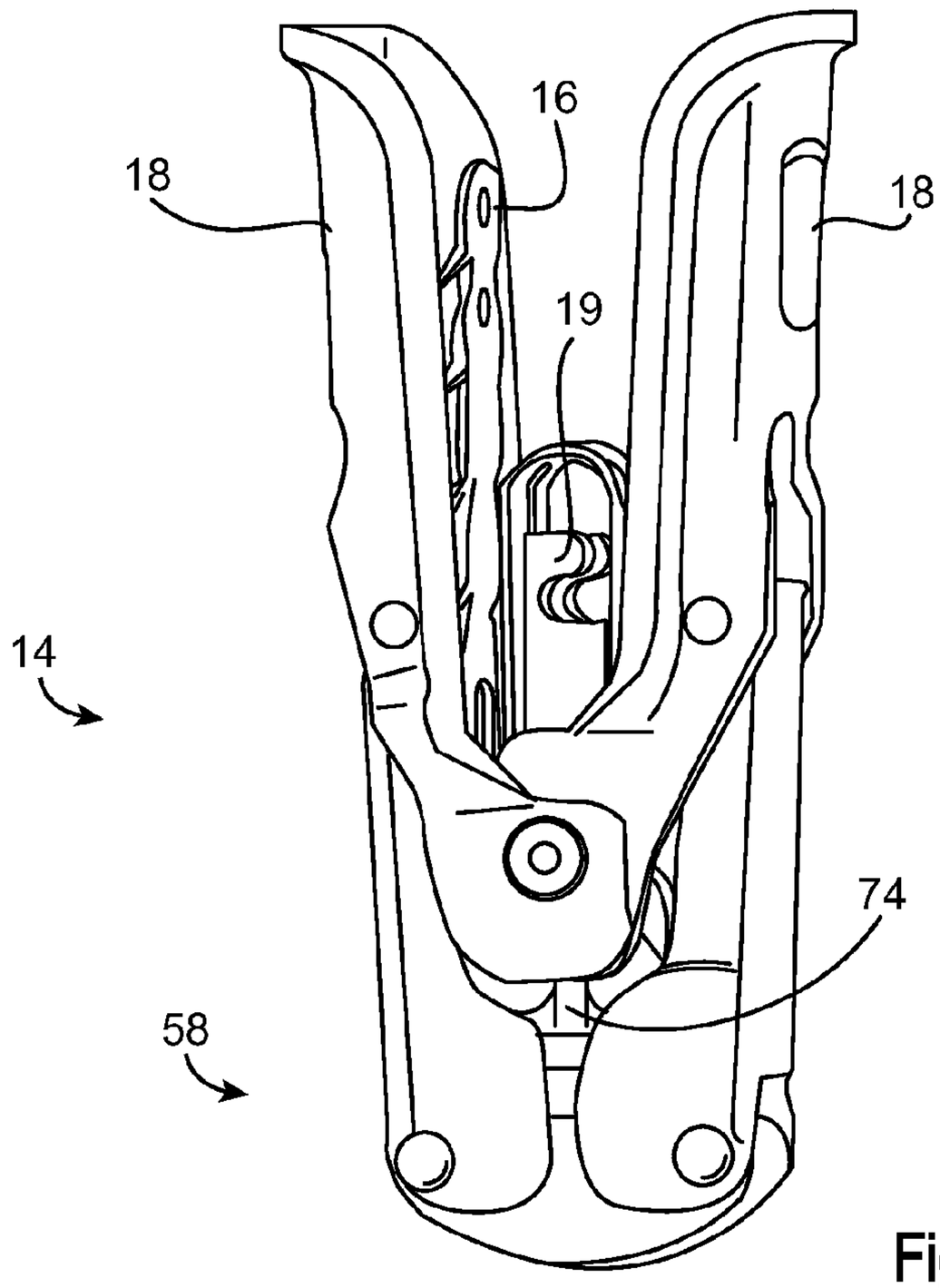

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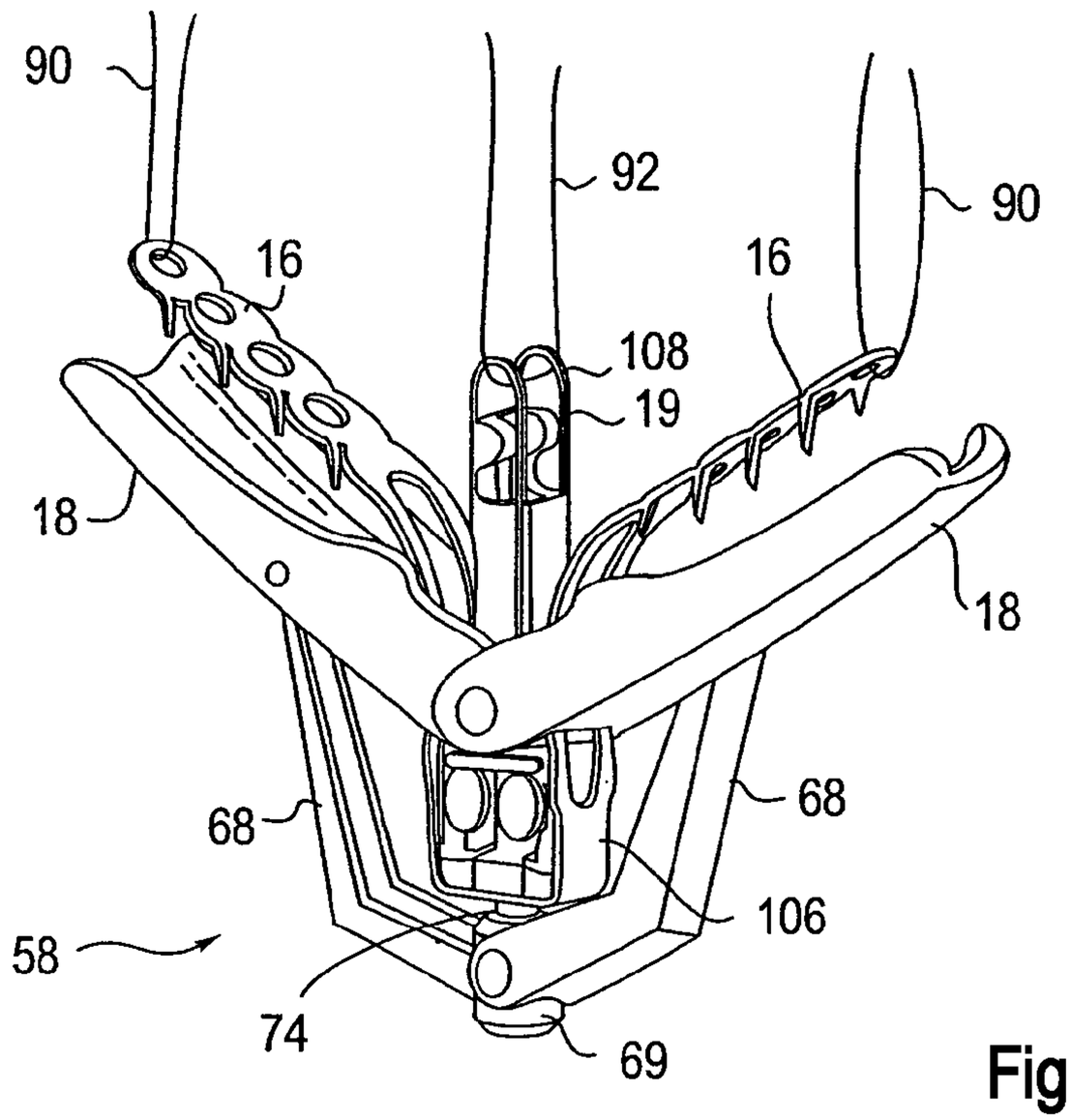
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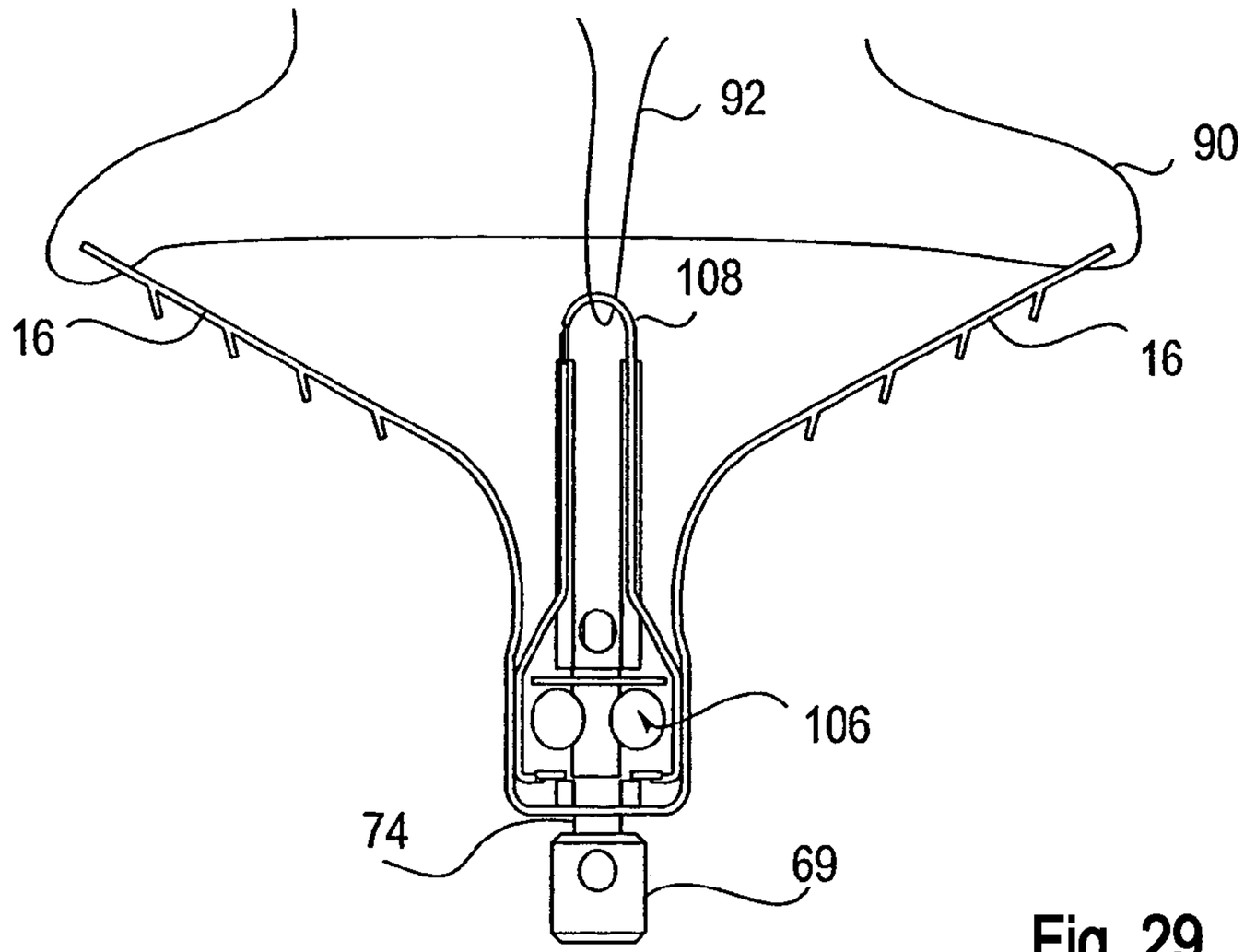
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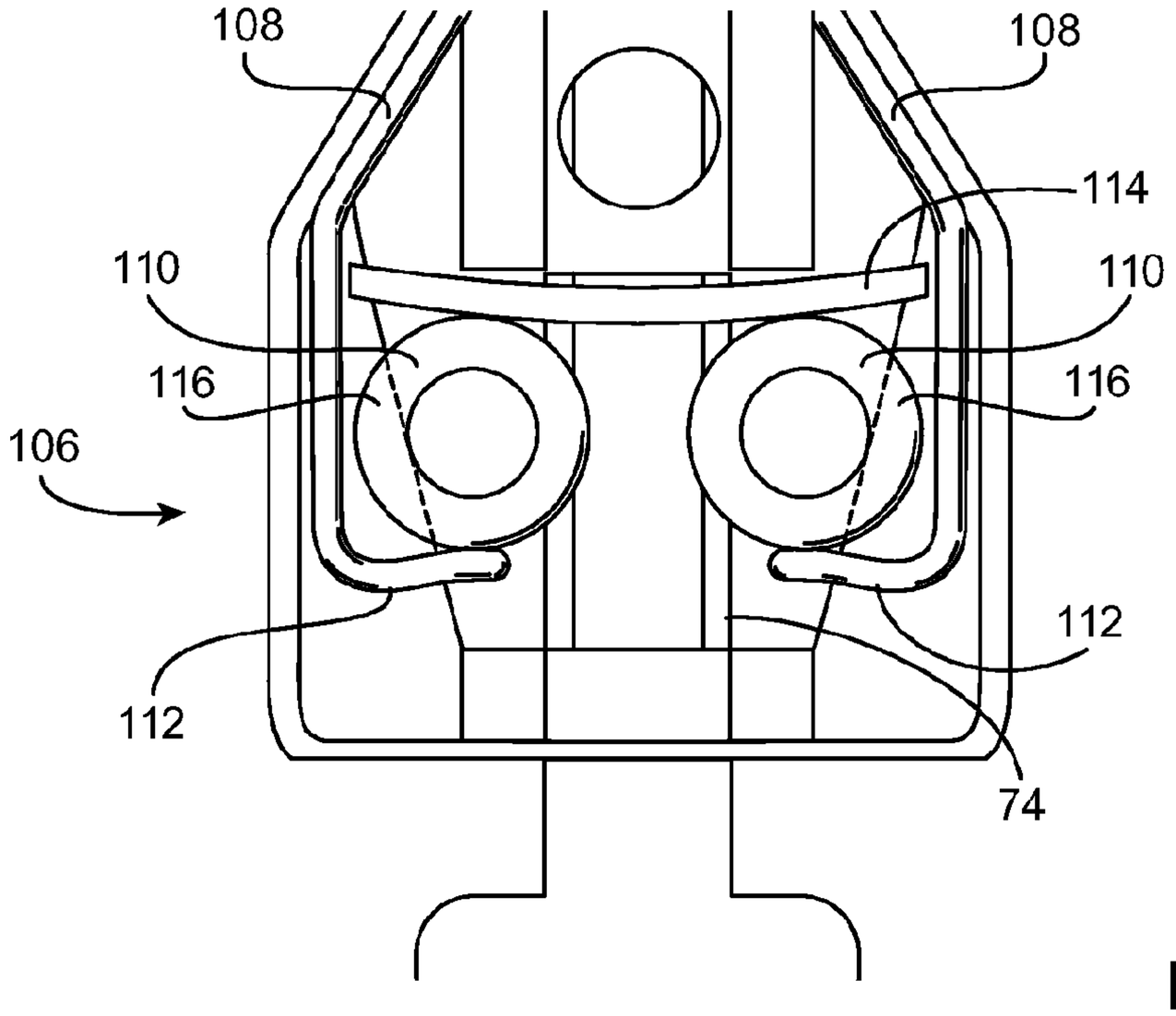
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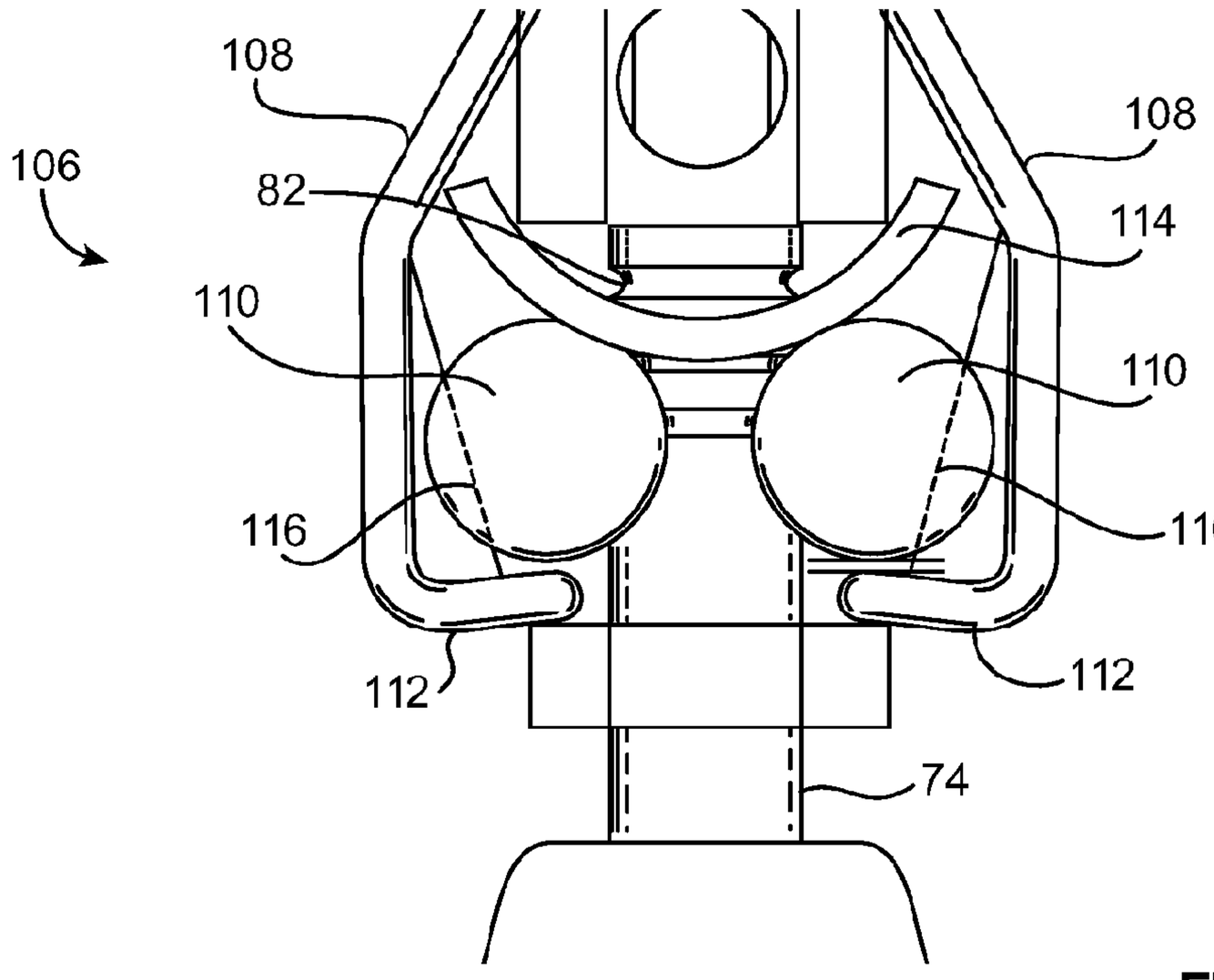
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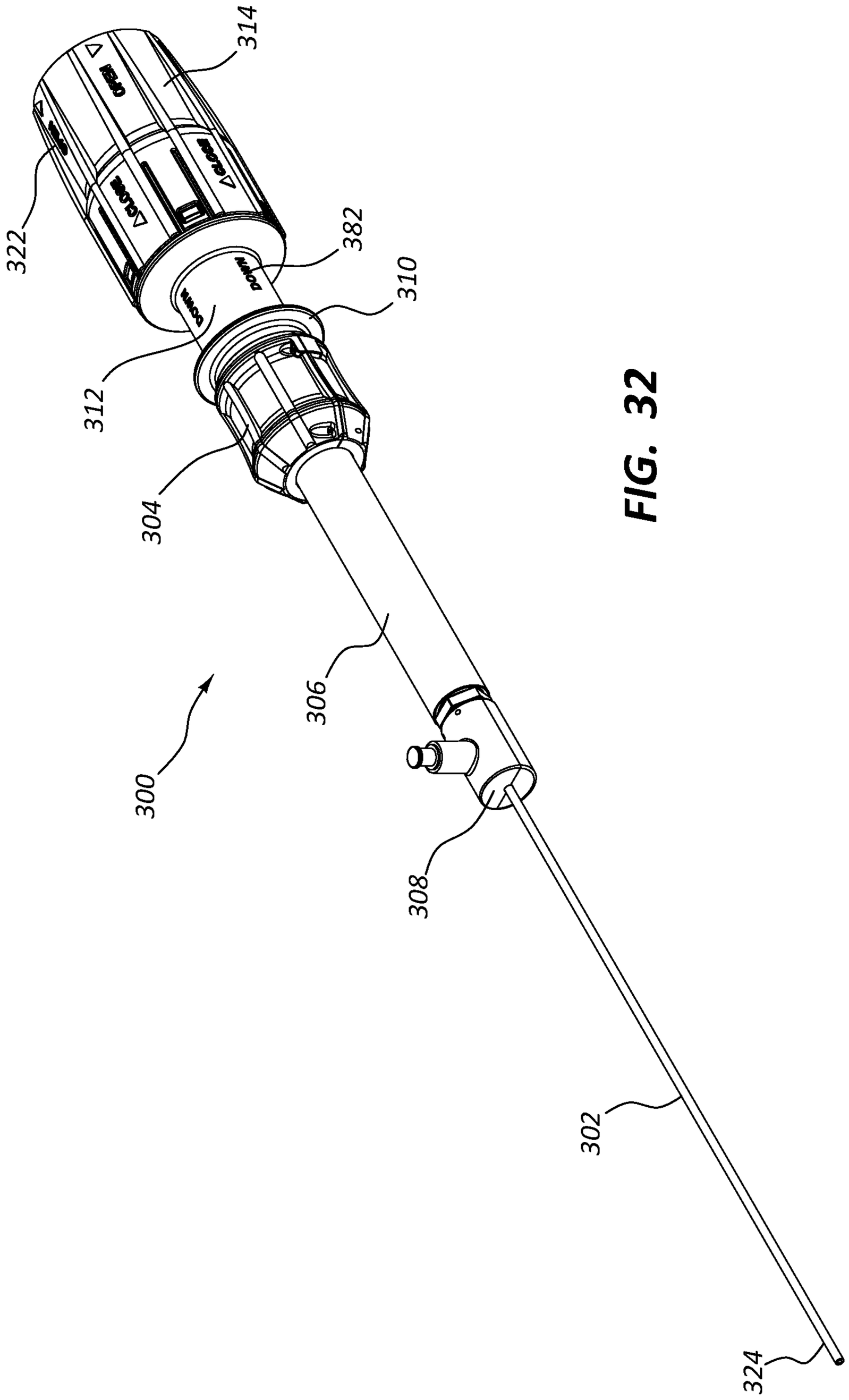

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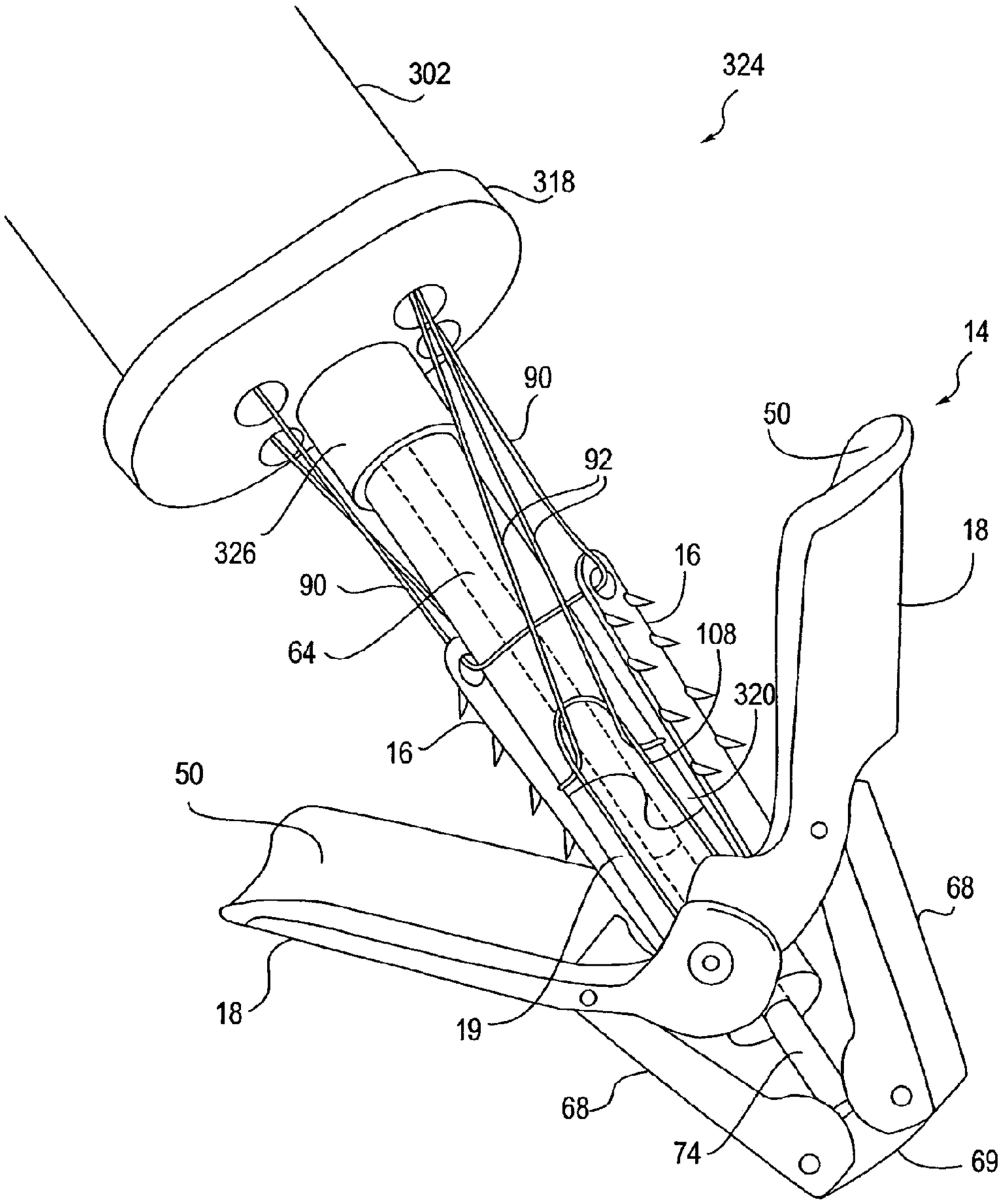
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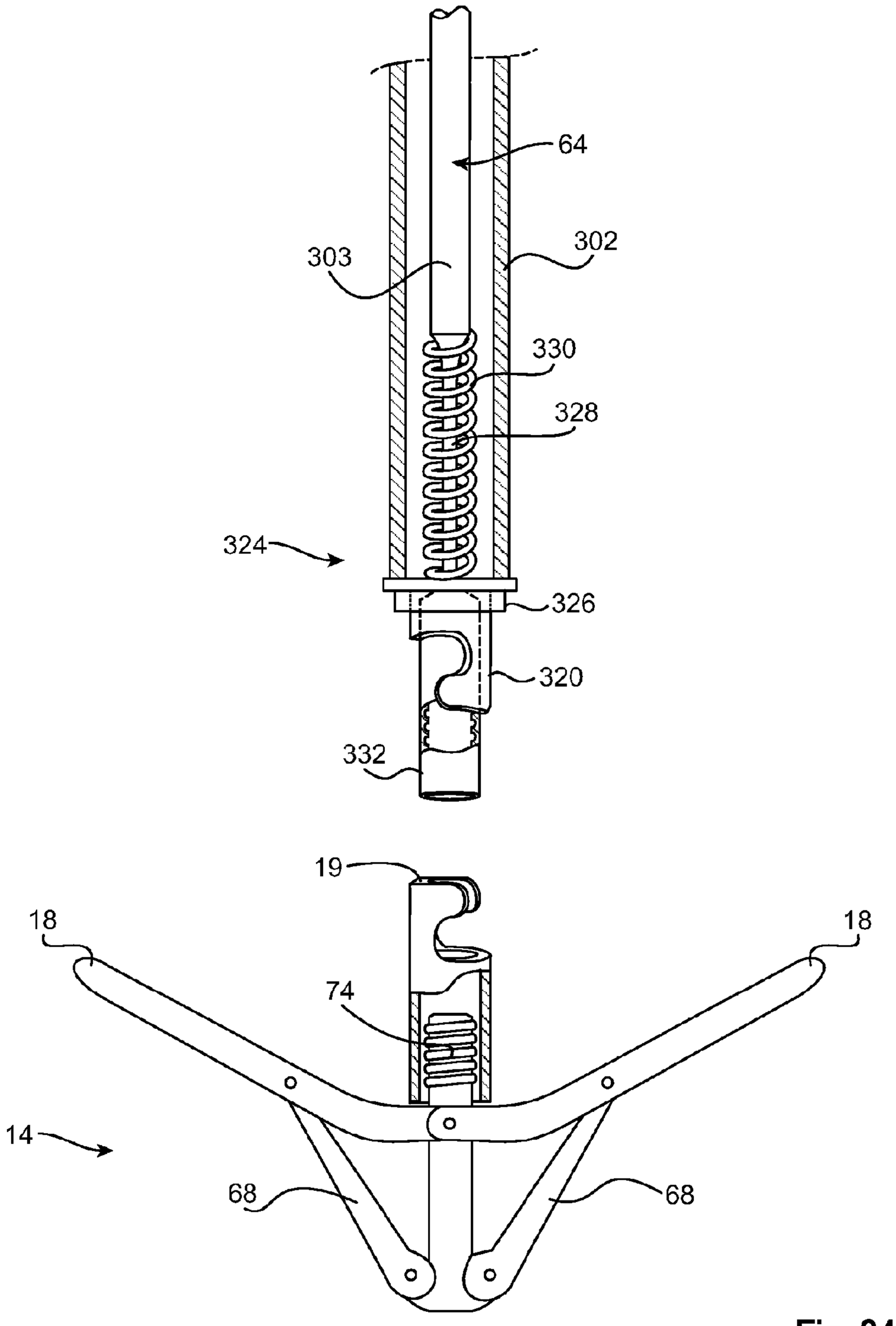
Fig. 33



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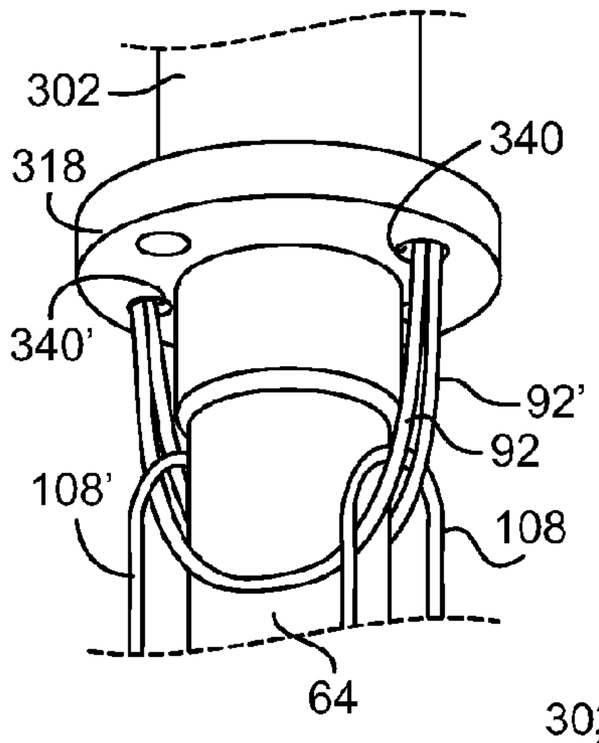

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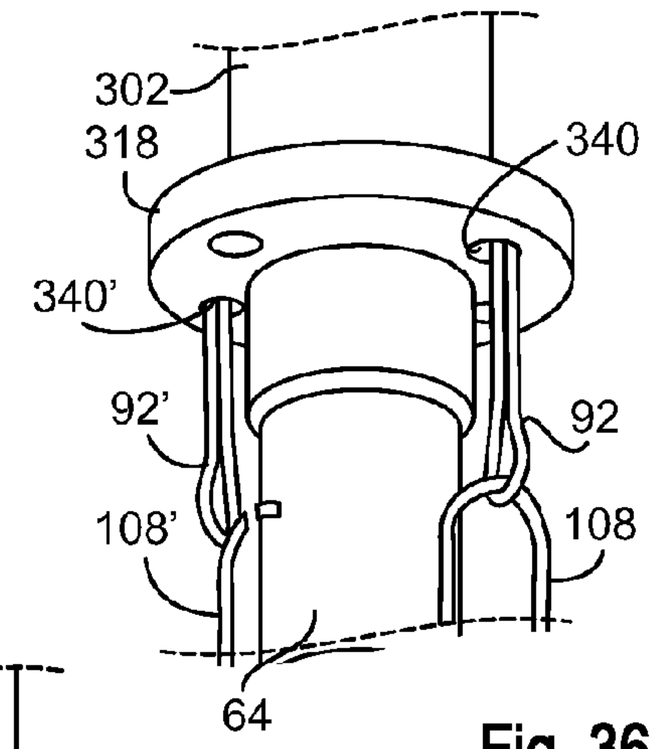

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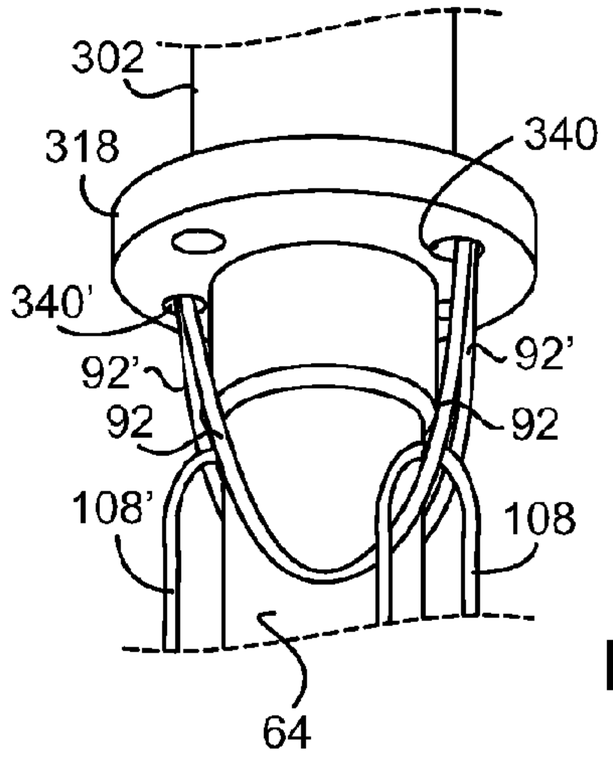

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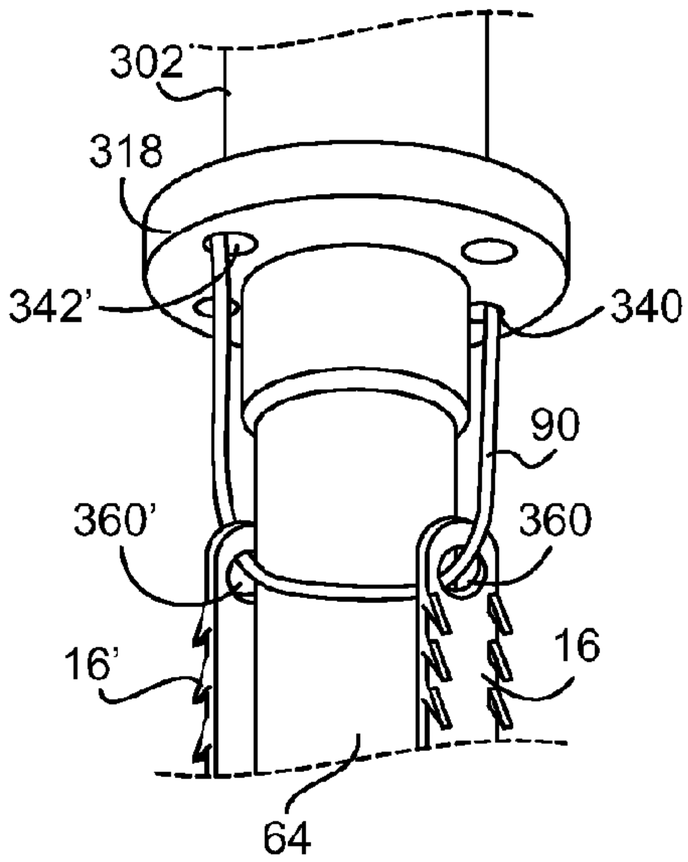

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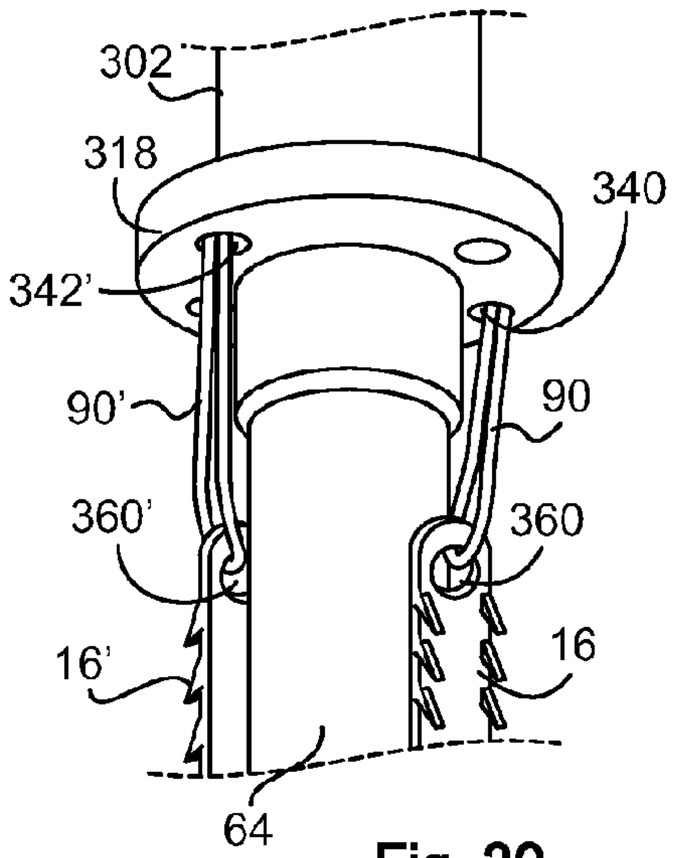

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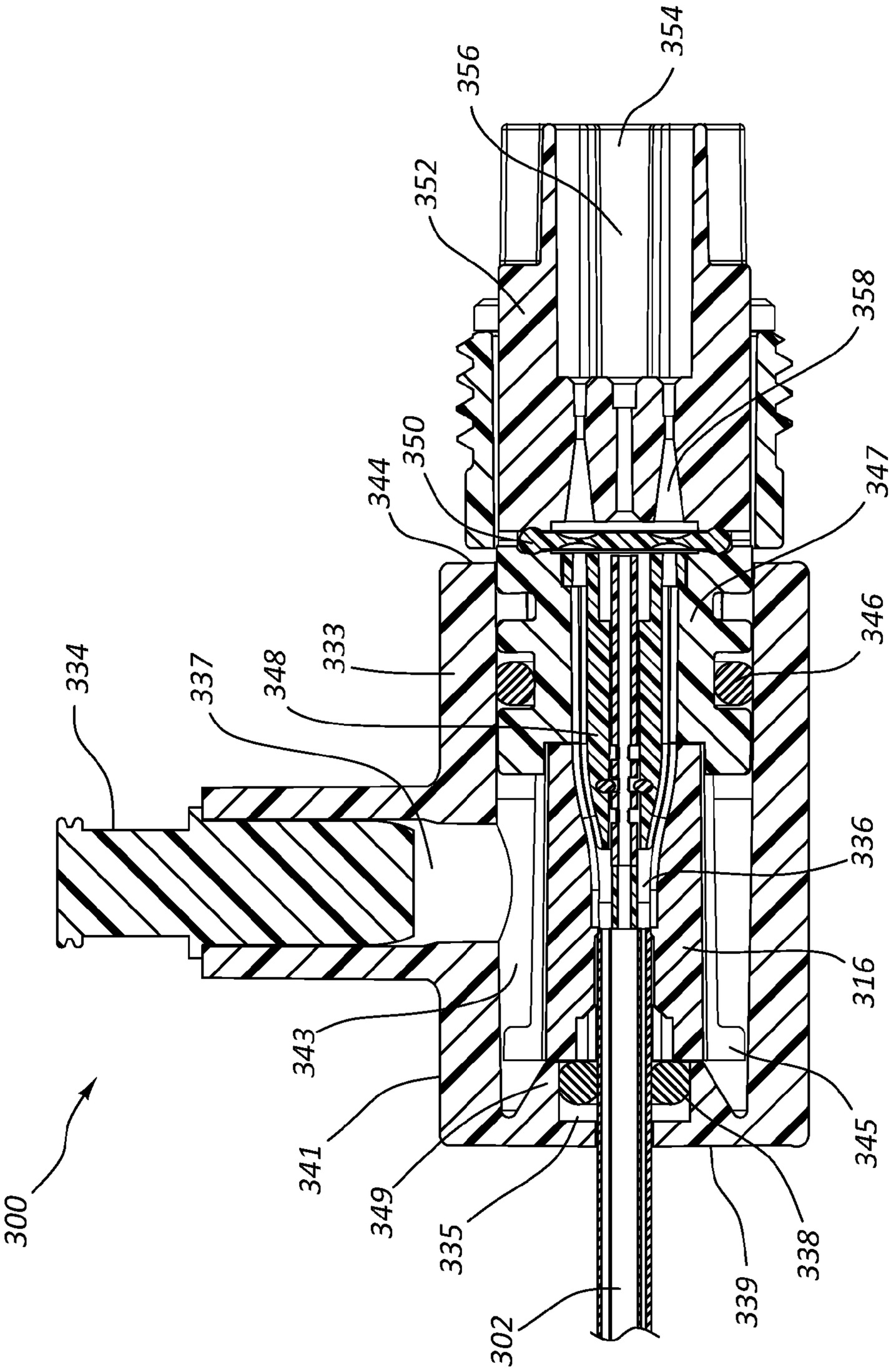
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FIG. 40

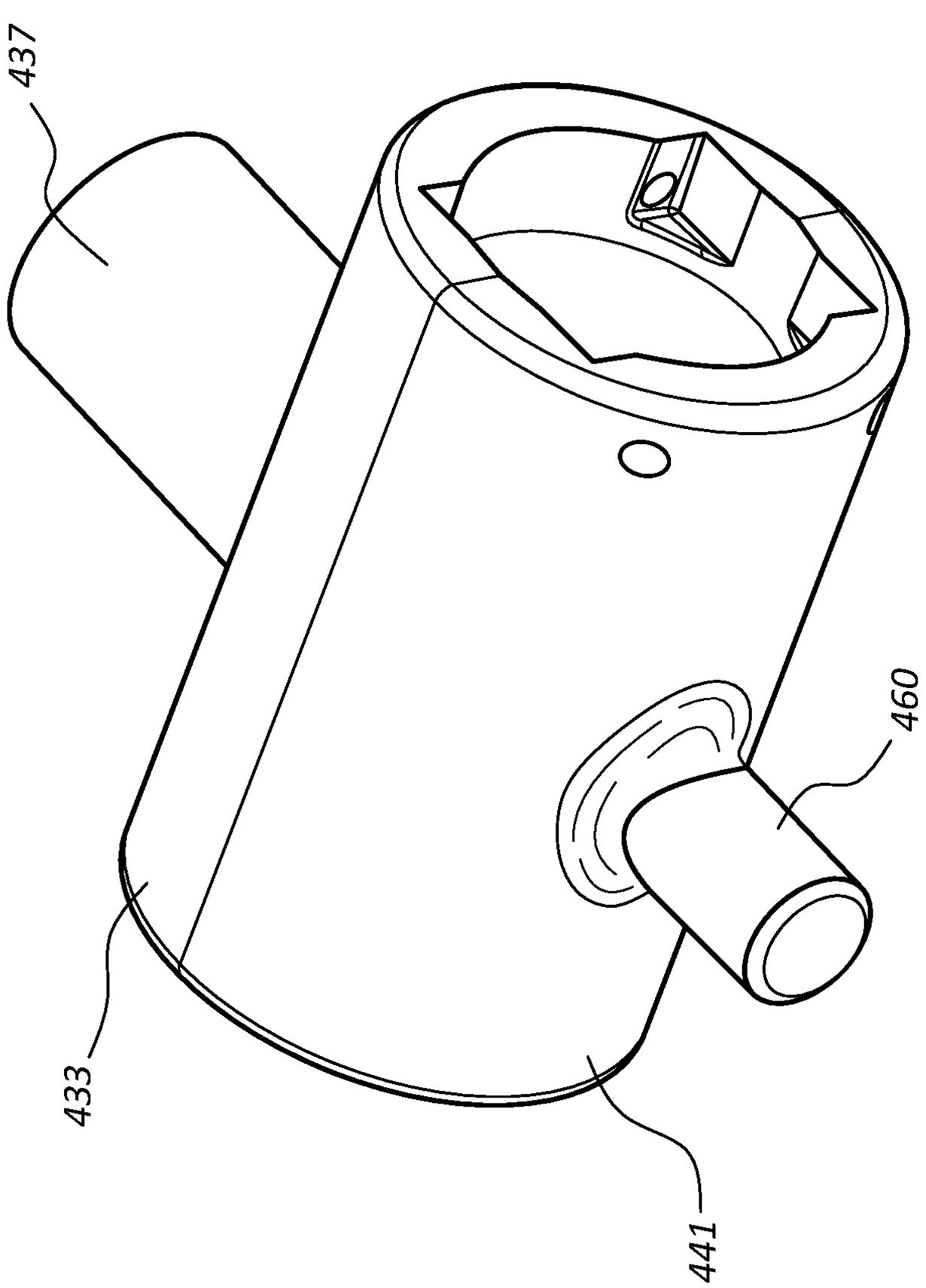

FIG. 41

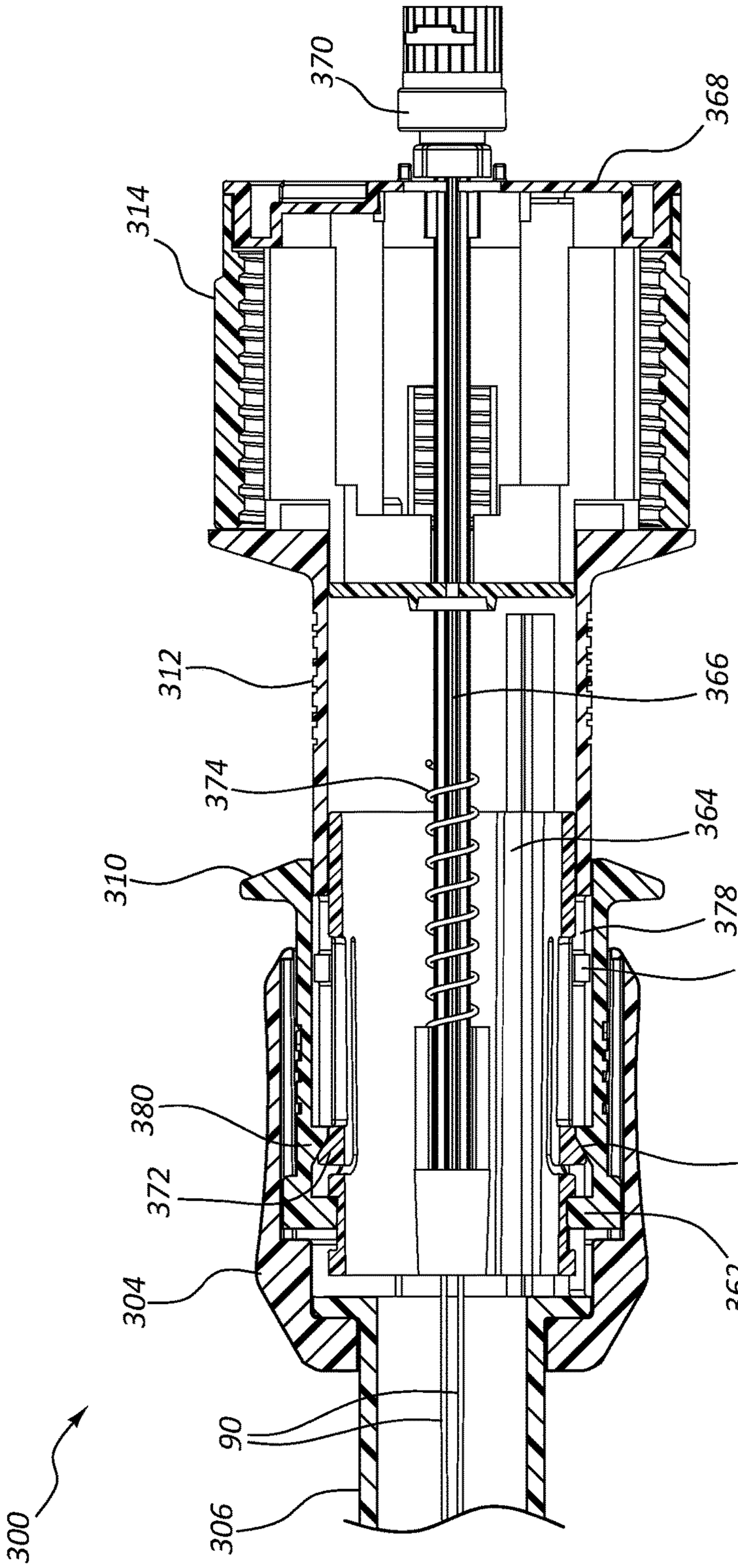
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FIG. 42

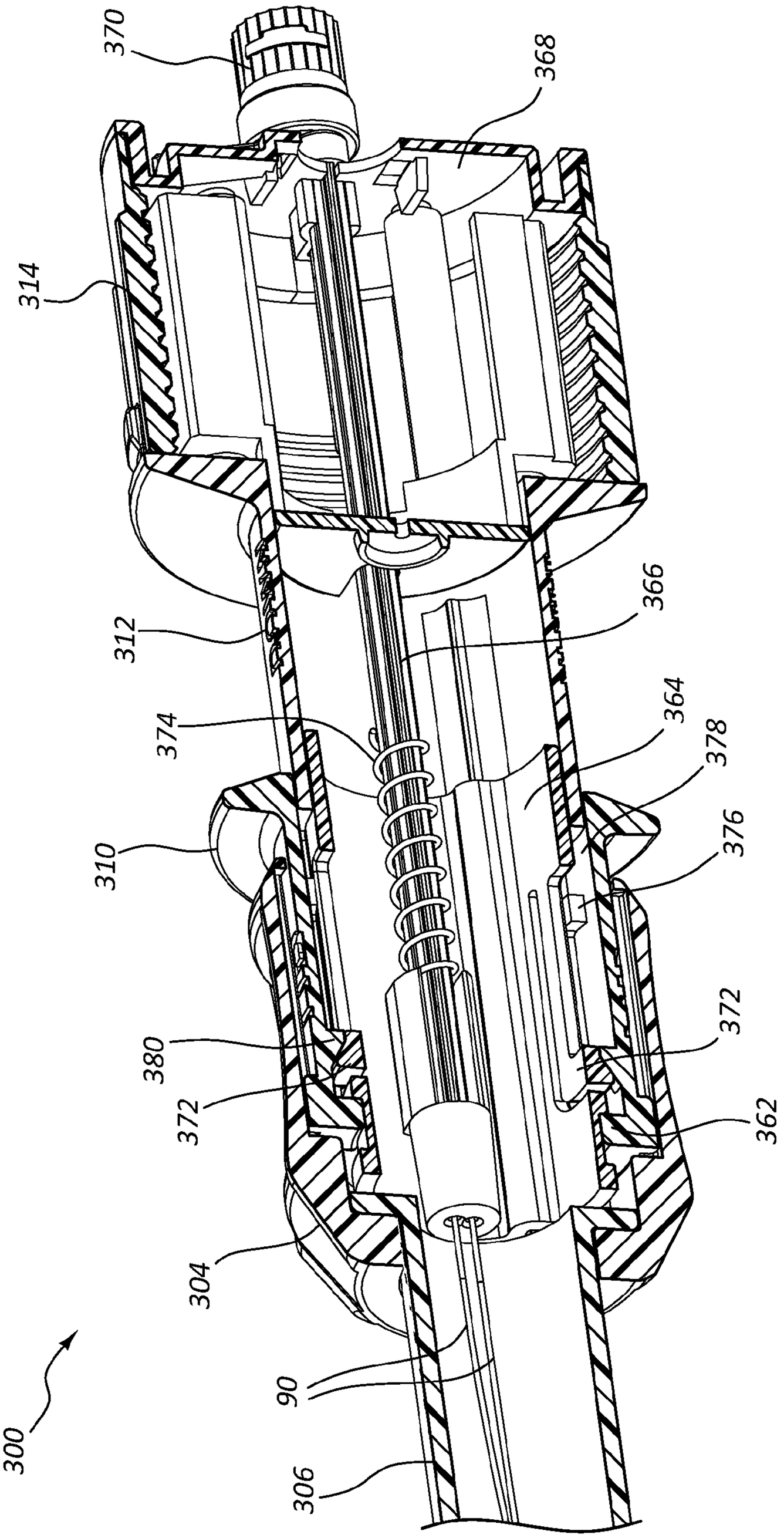
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FIG. 43

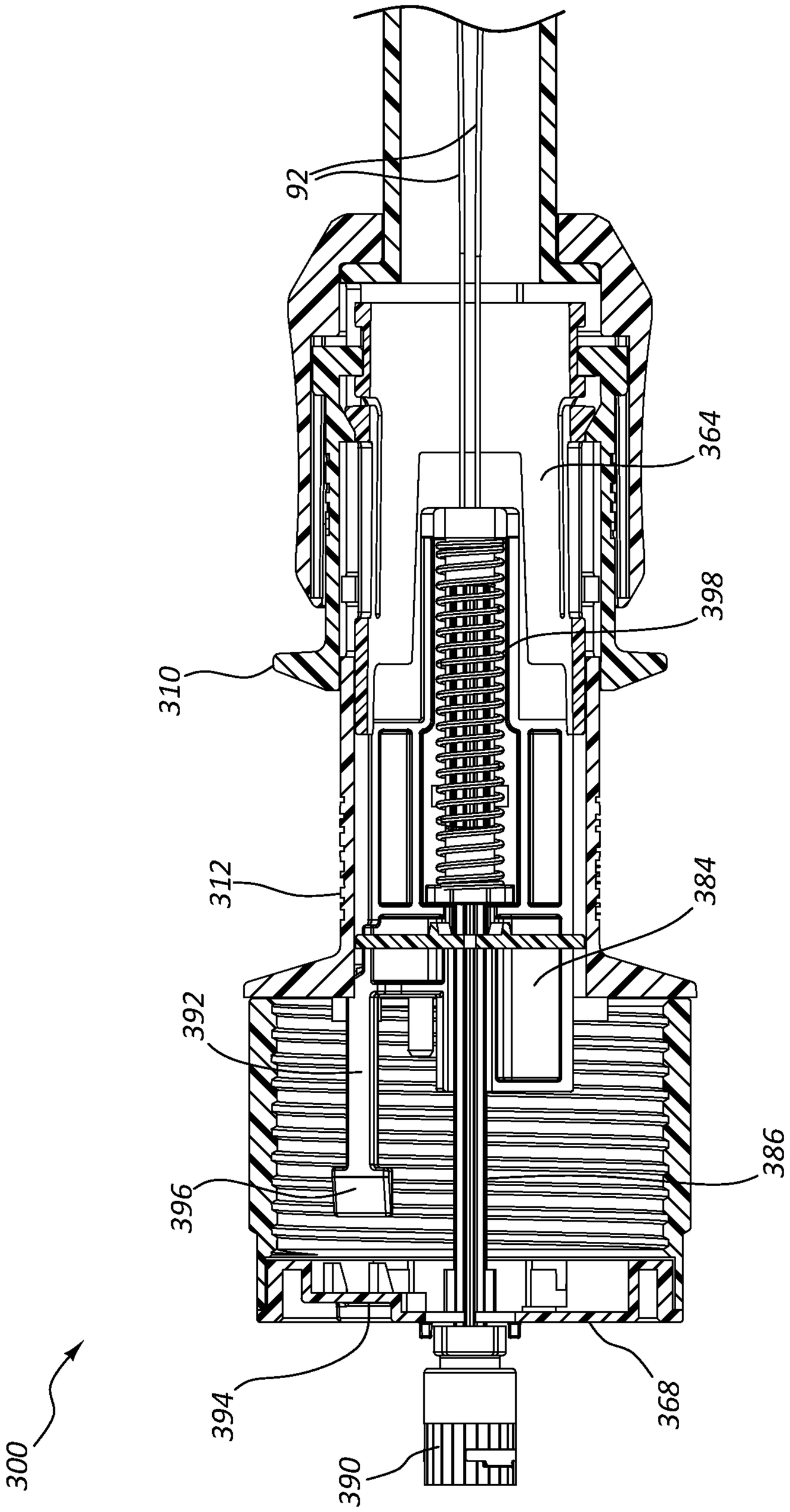

FIG. 44

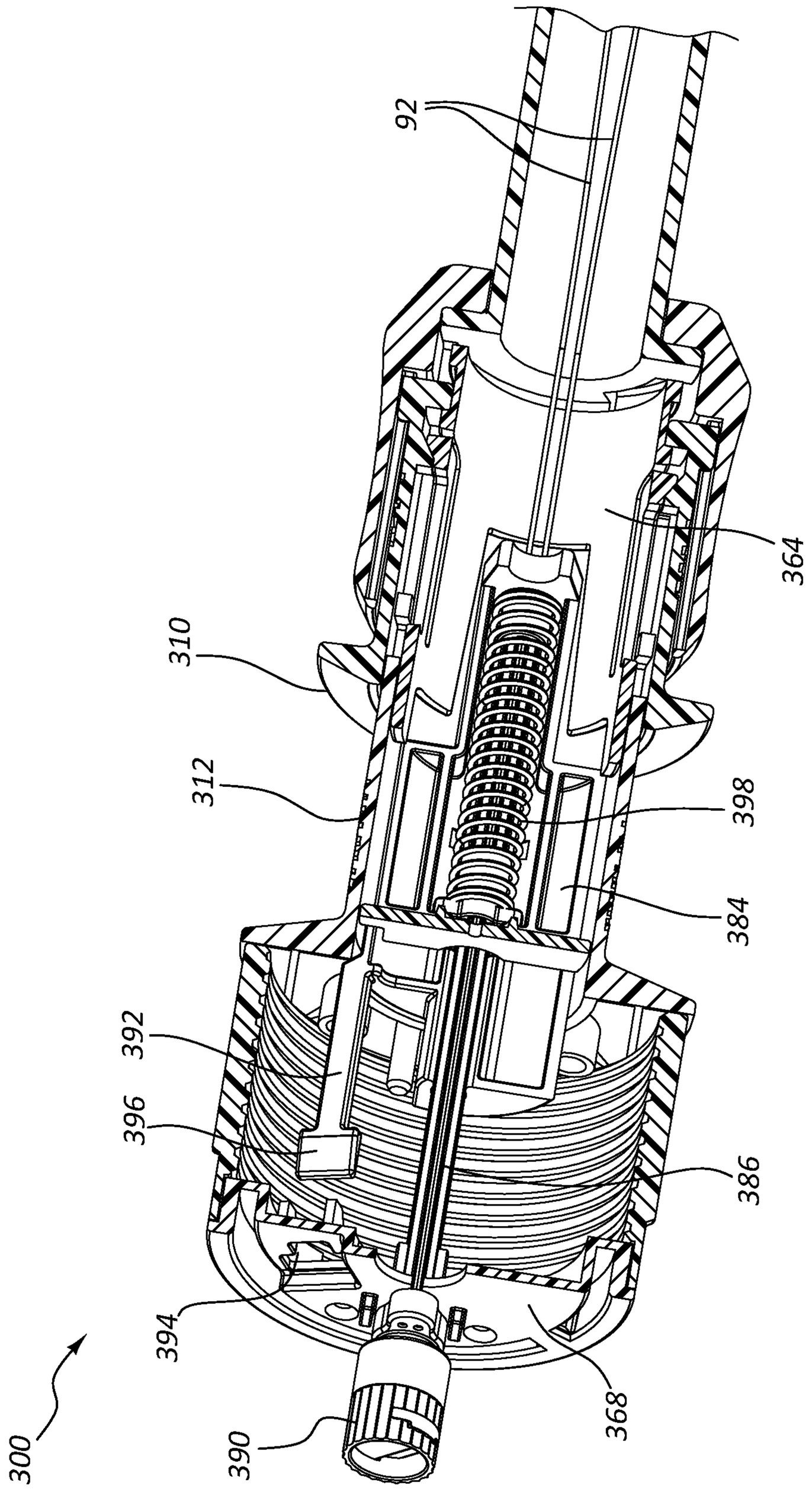

FIG. 45

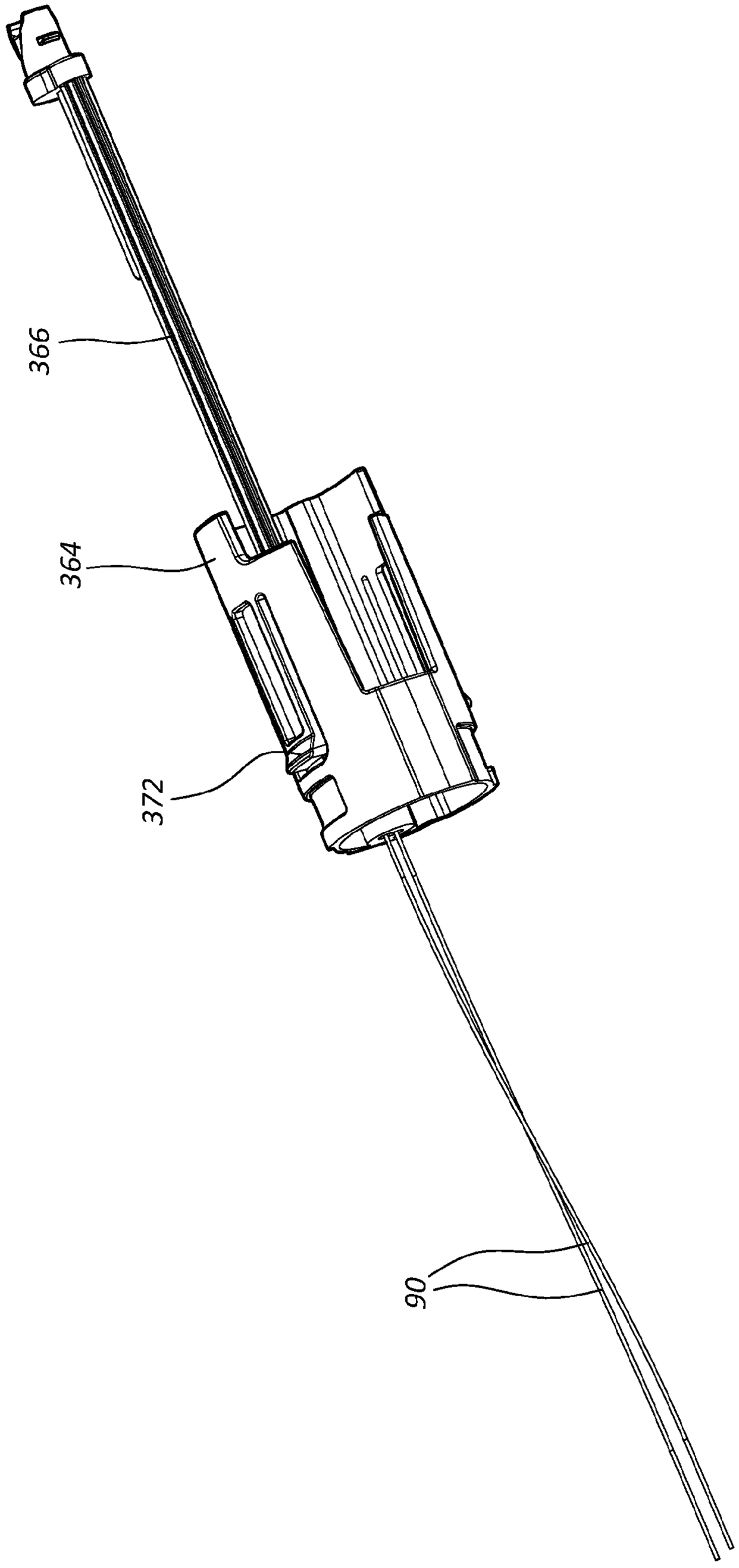

FIG. 46

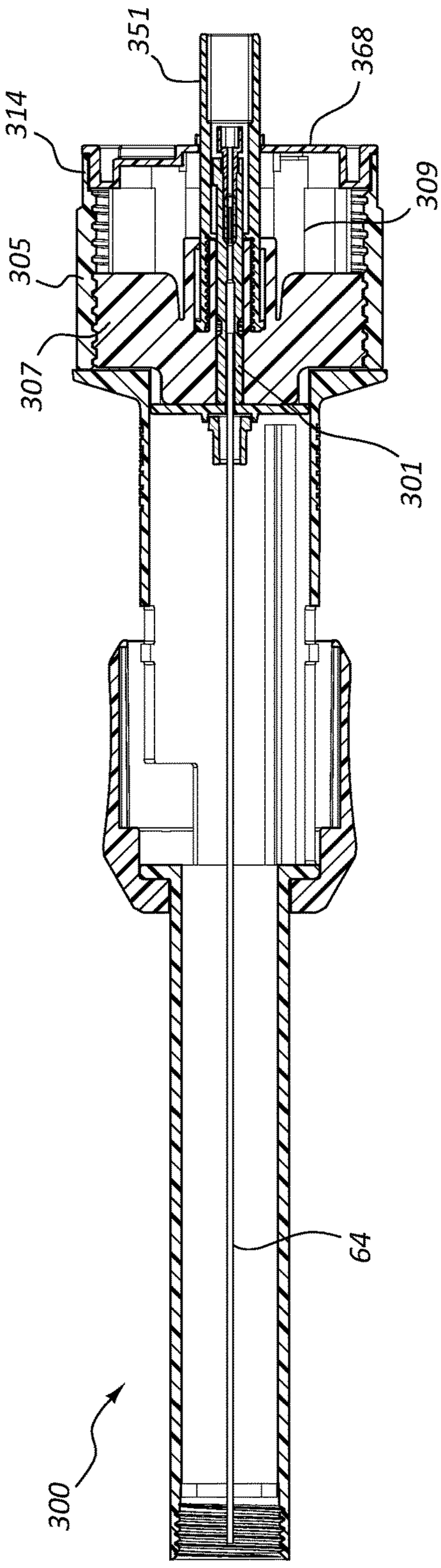
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FIG. 47

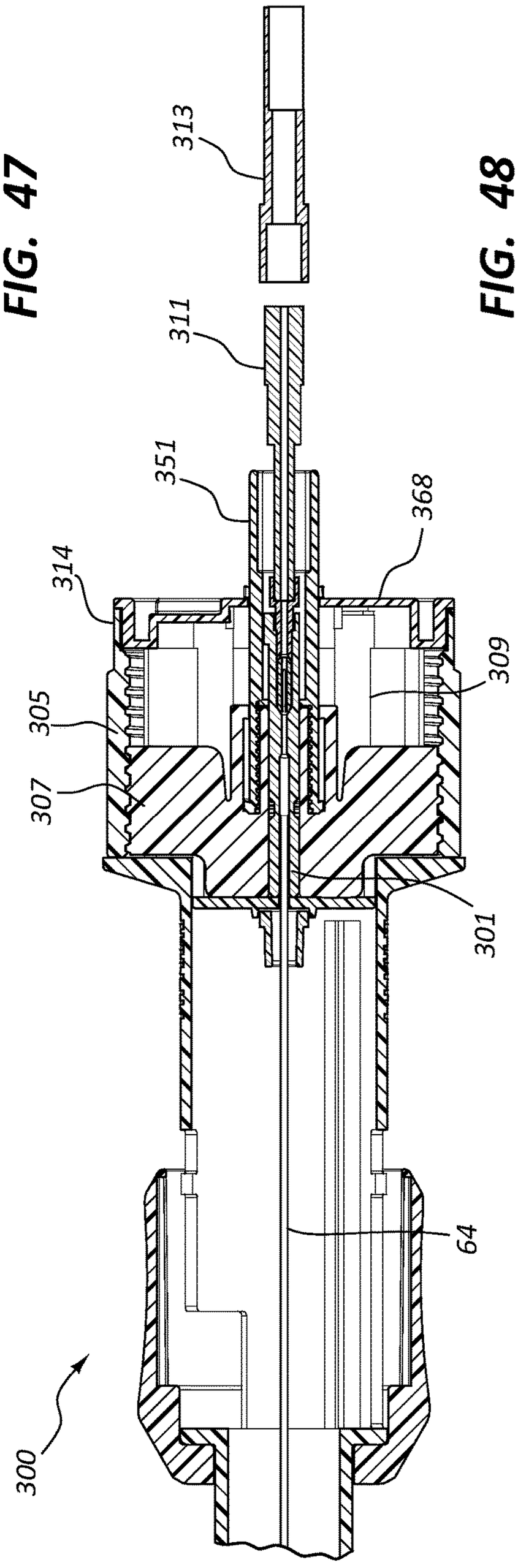
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FIG. 48

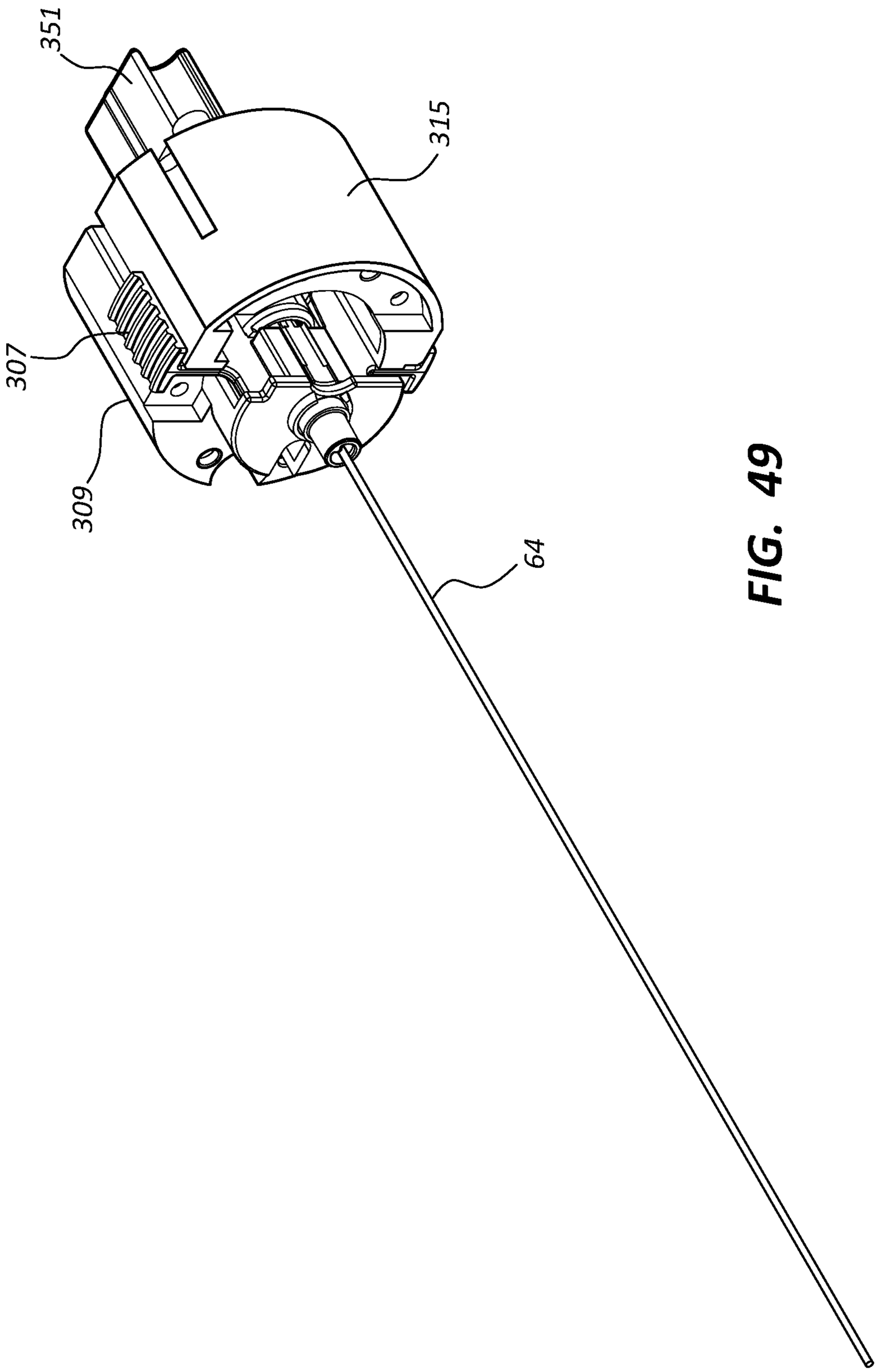


FIG. 49

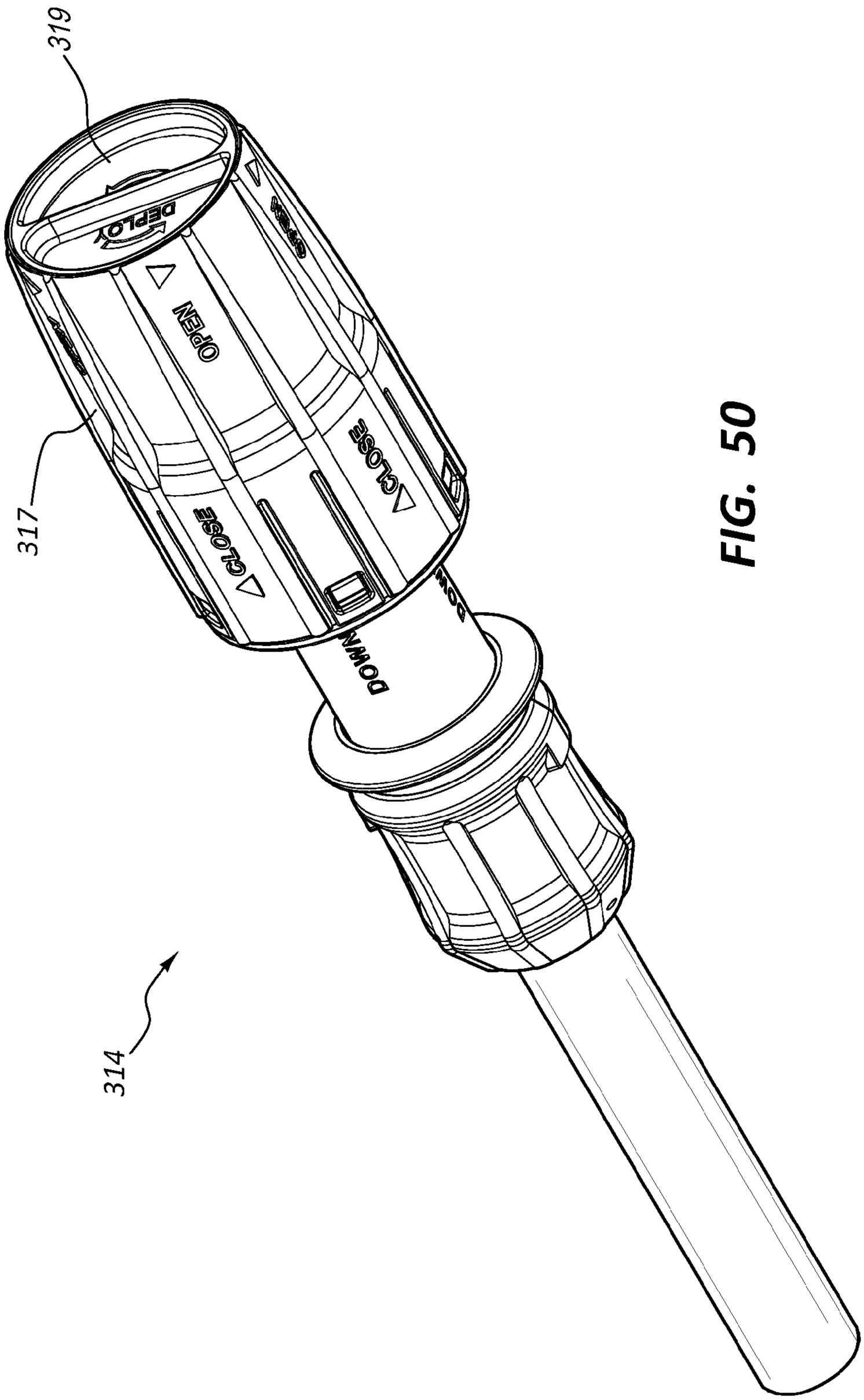


FIG. 50

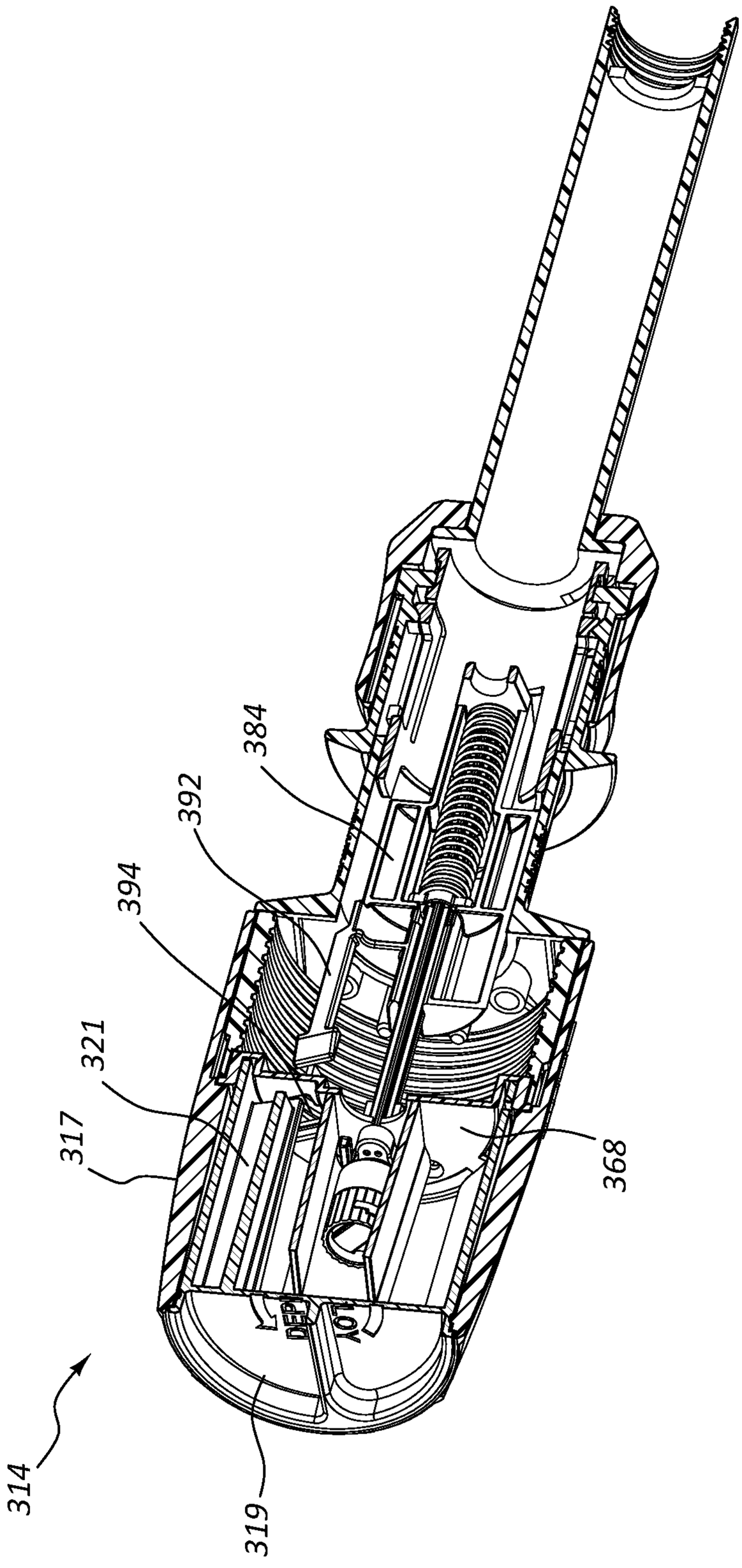


FIG. 51

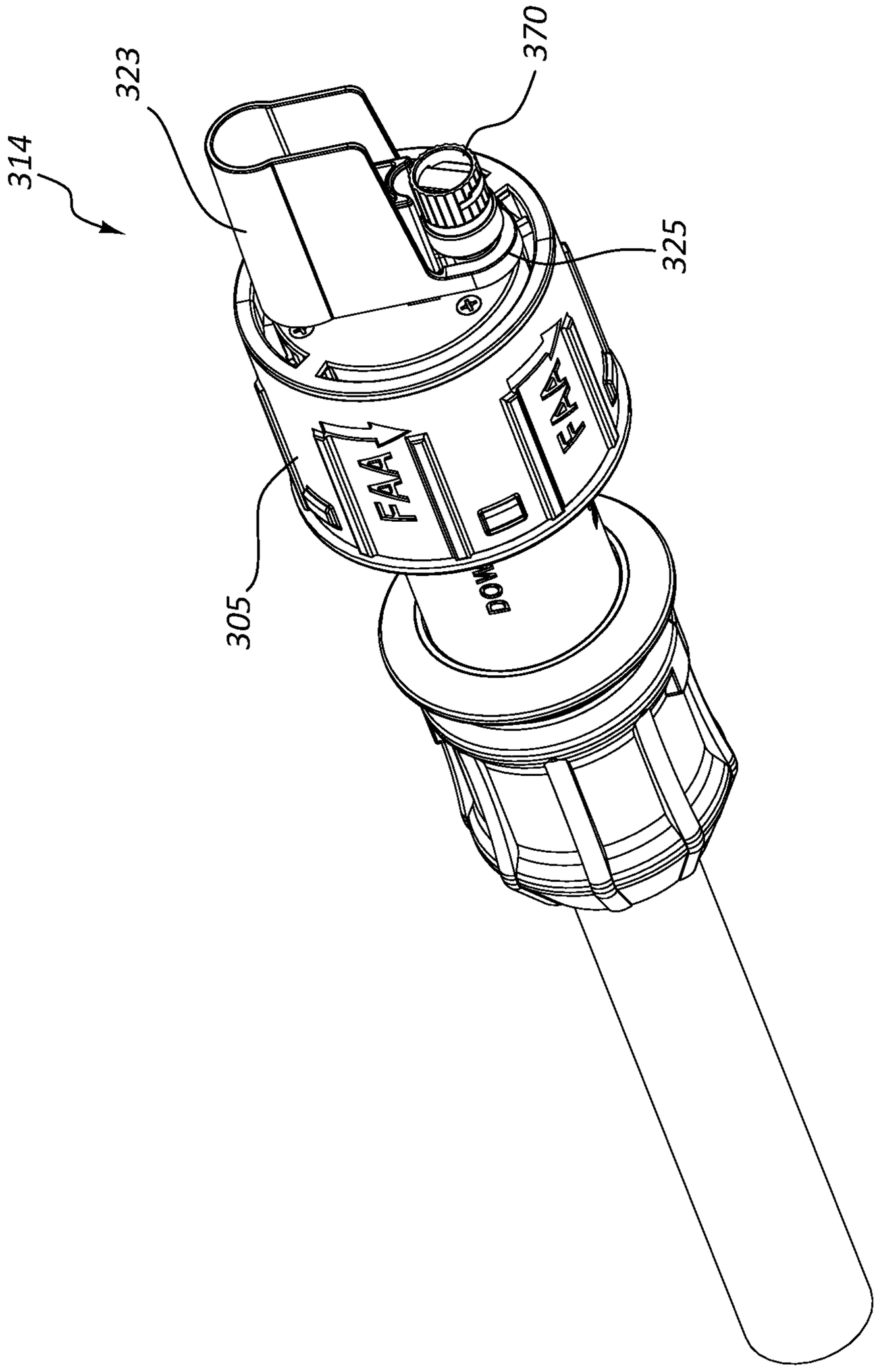


FIG. 52

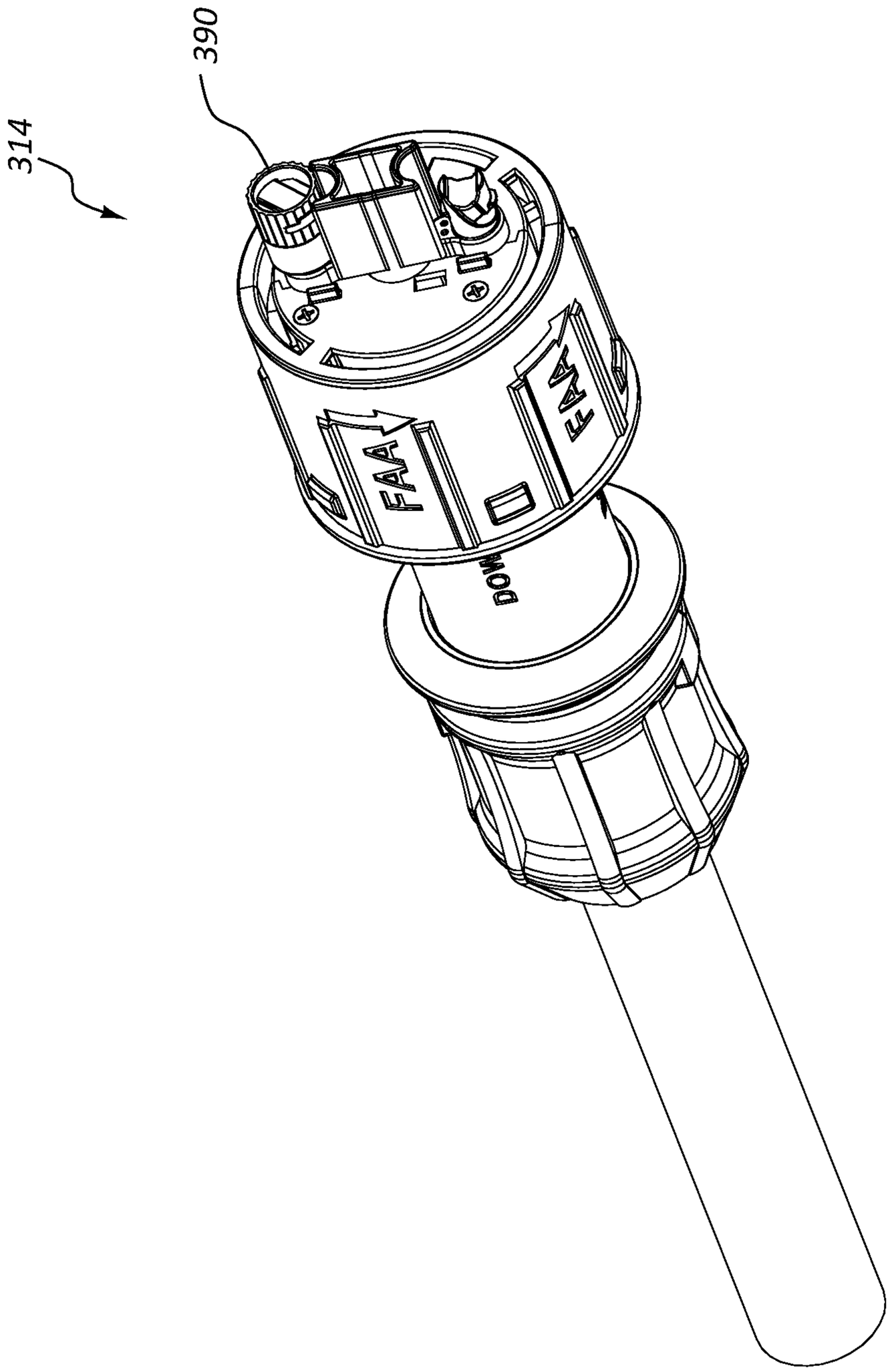


FIG. 53

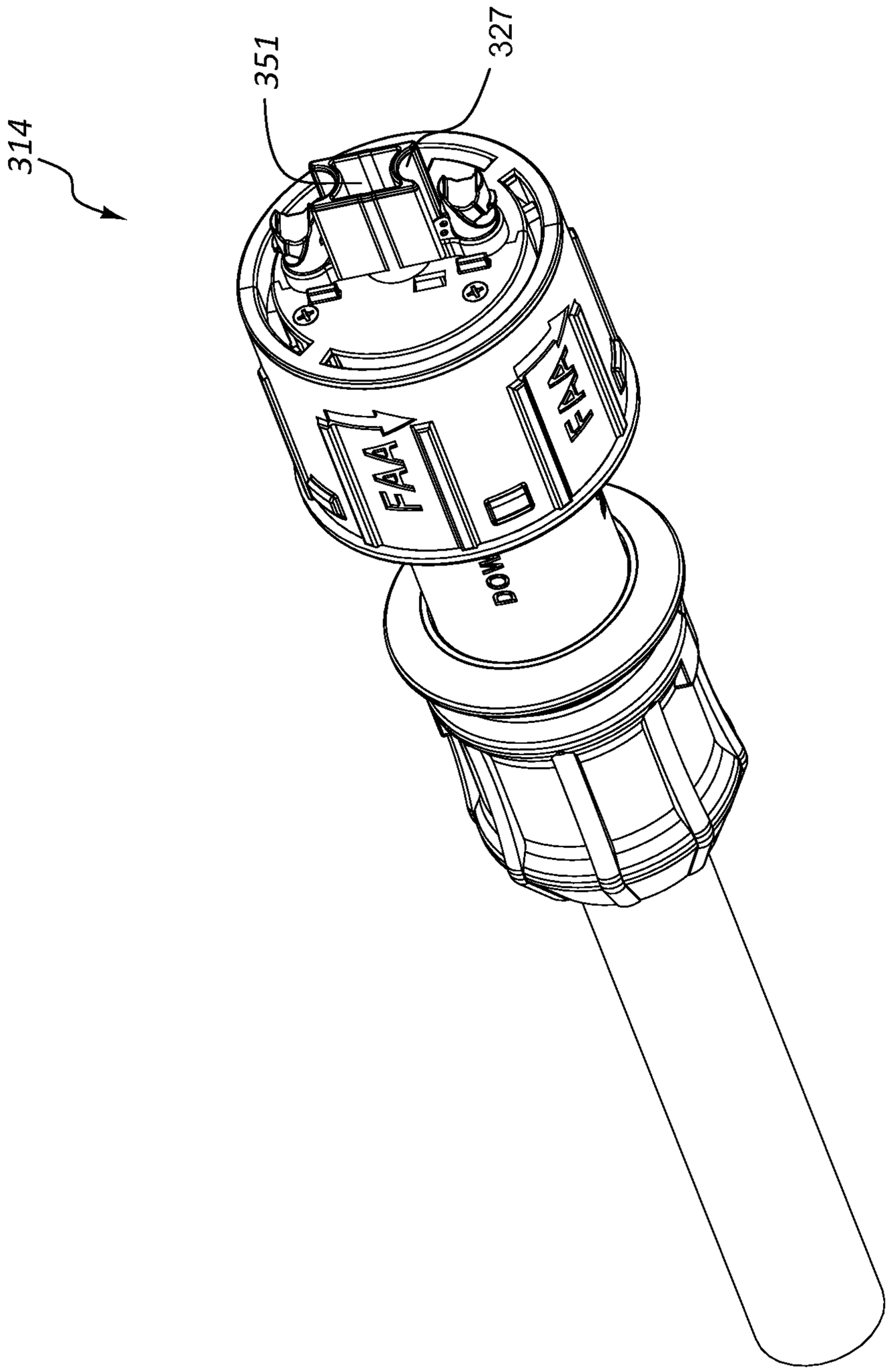


FIG. 54

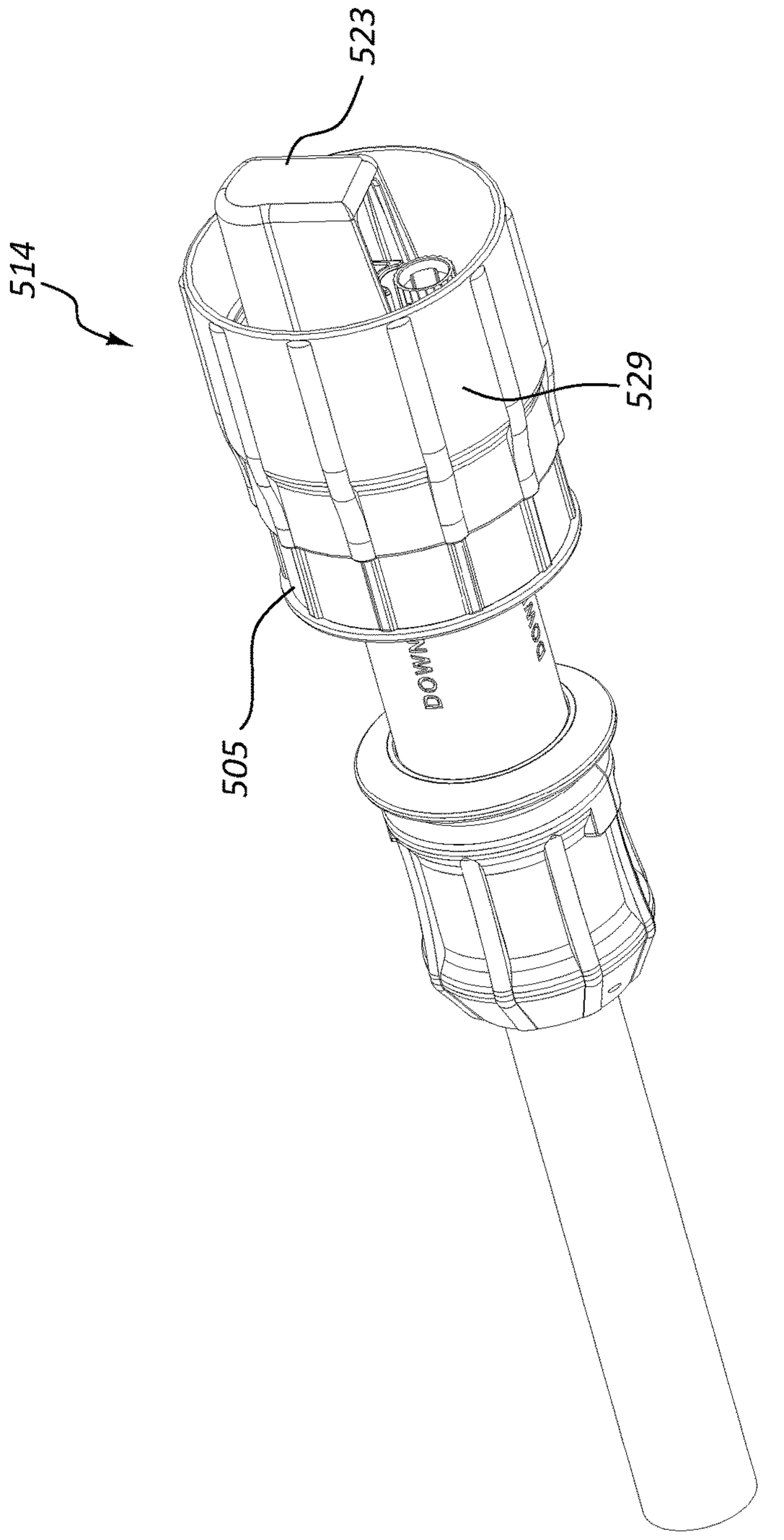


FIG. 55

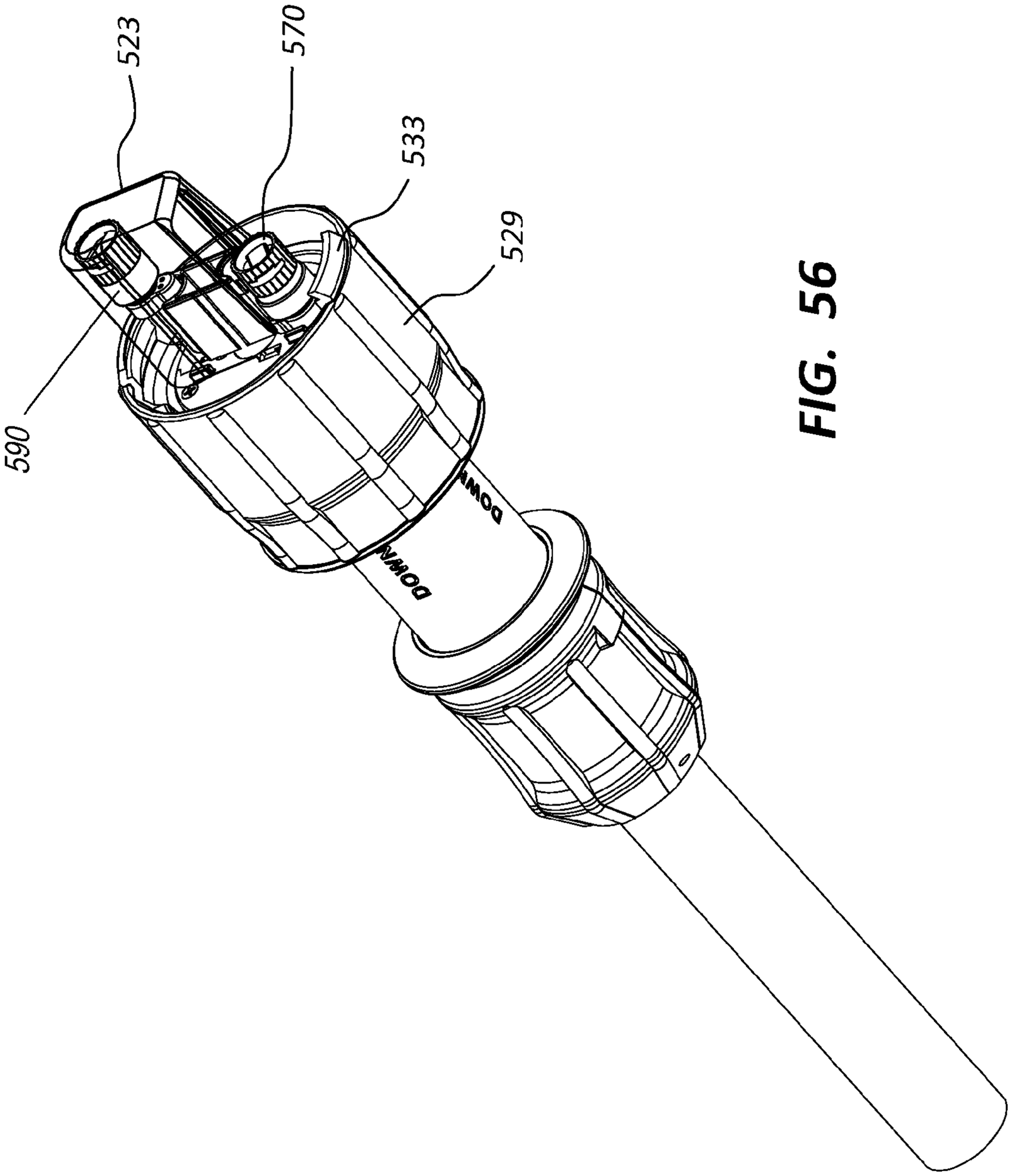


FIG. 56

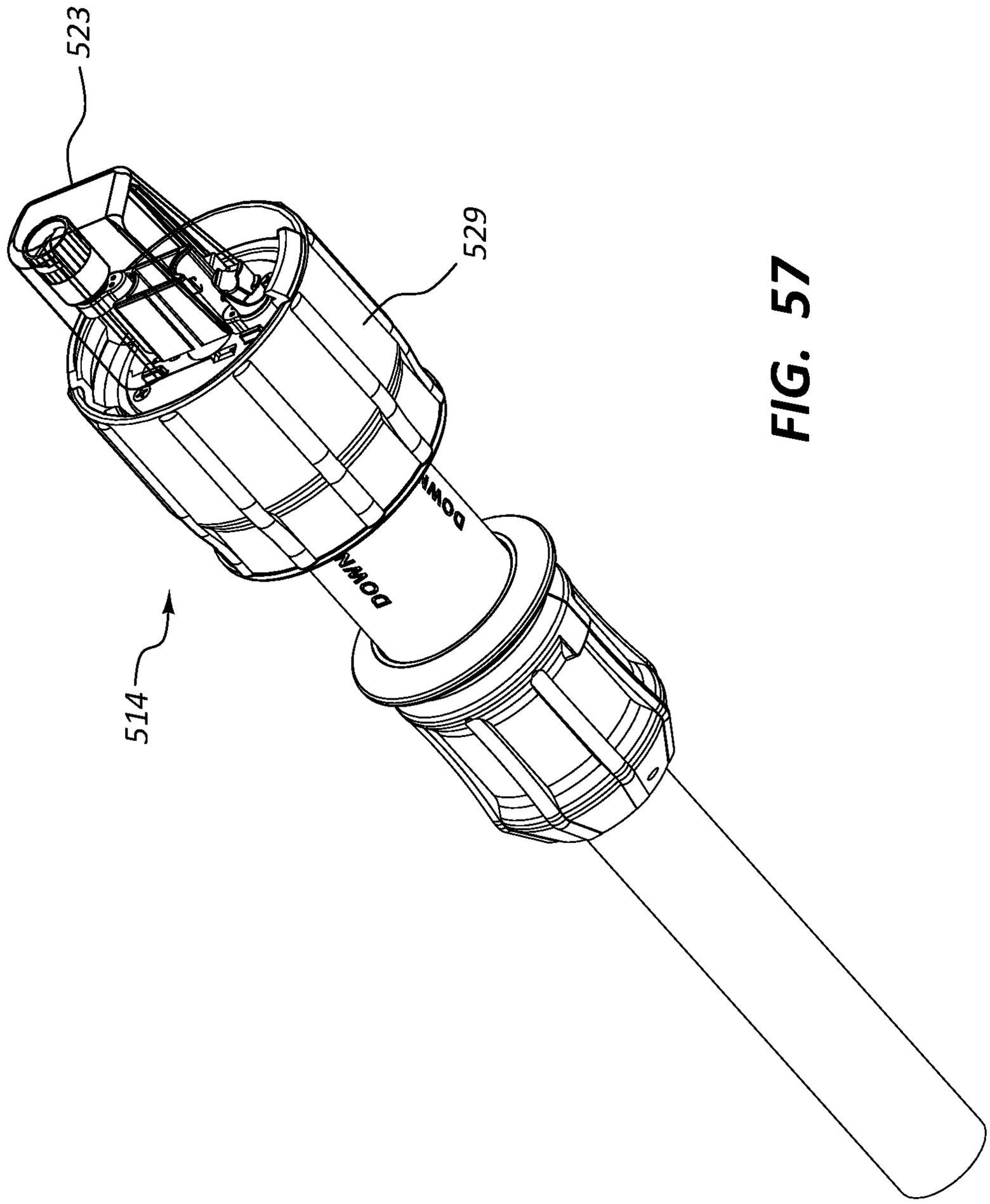


FIG. 57

FIG. 58

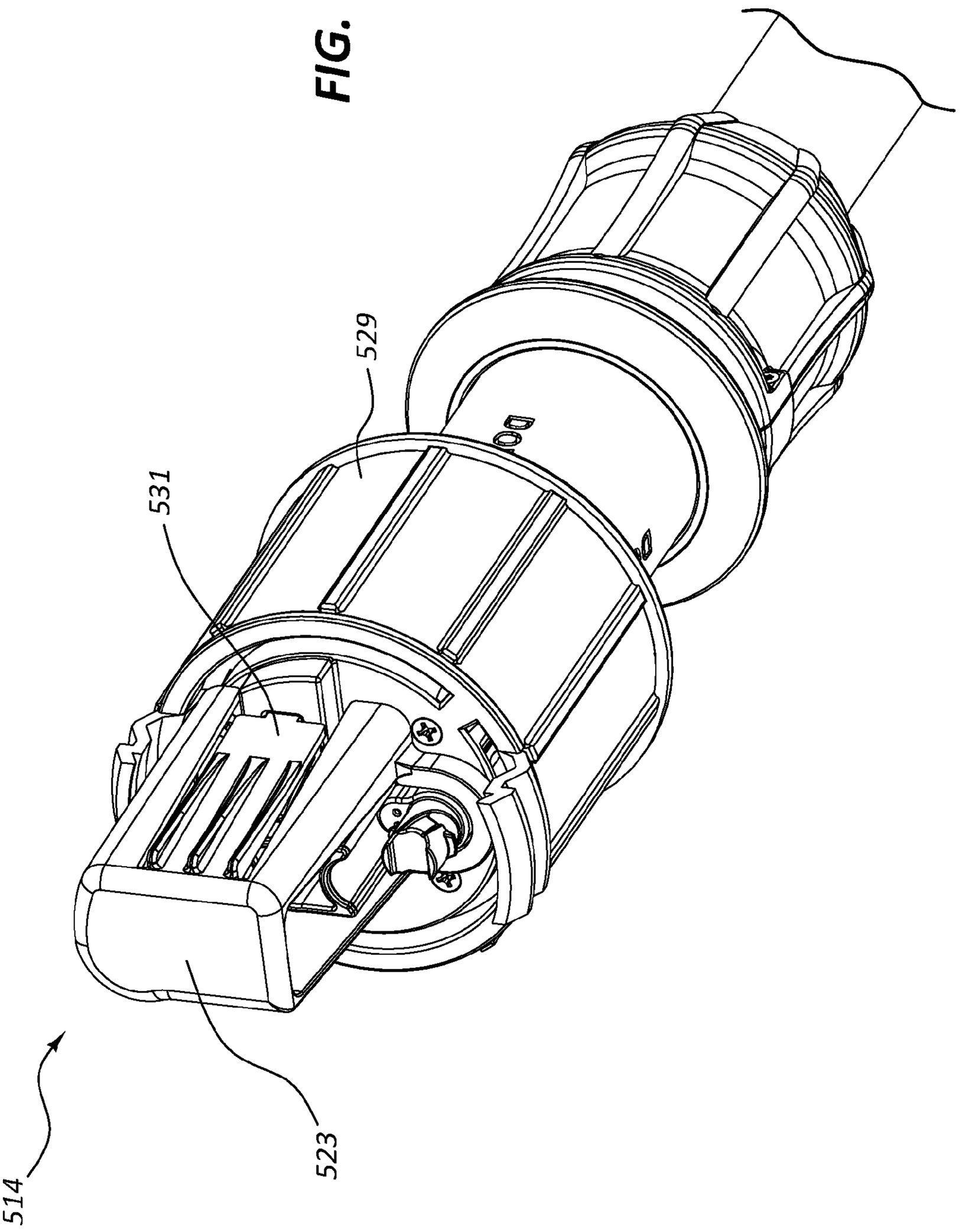
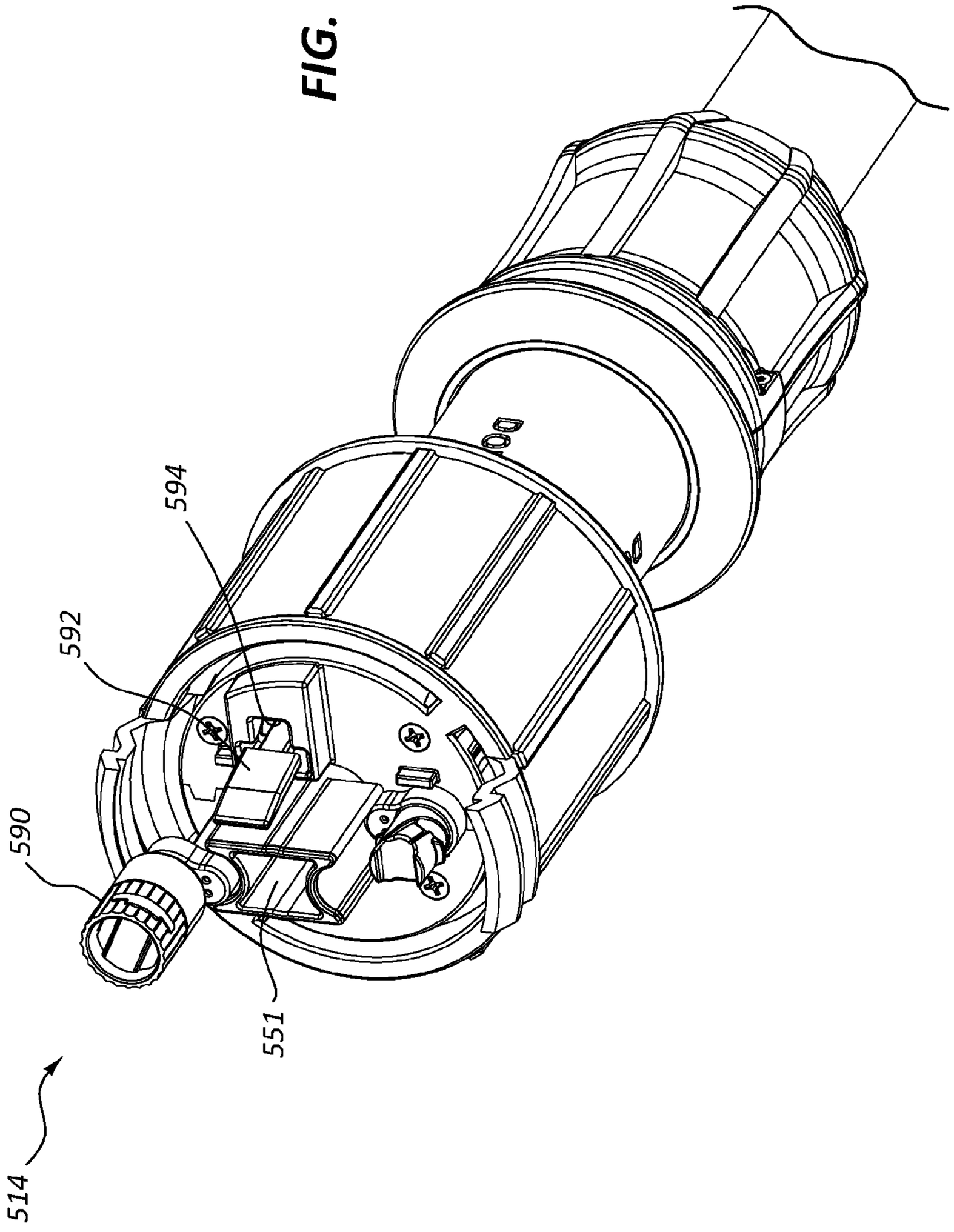


FIG. 59



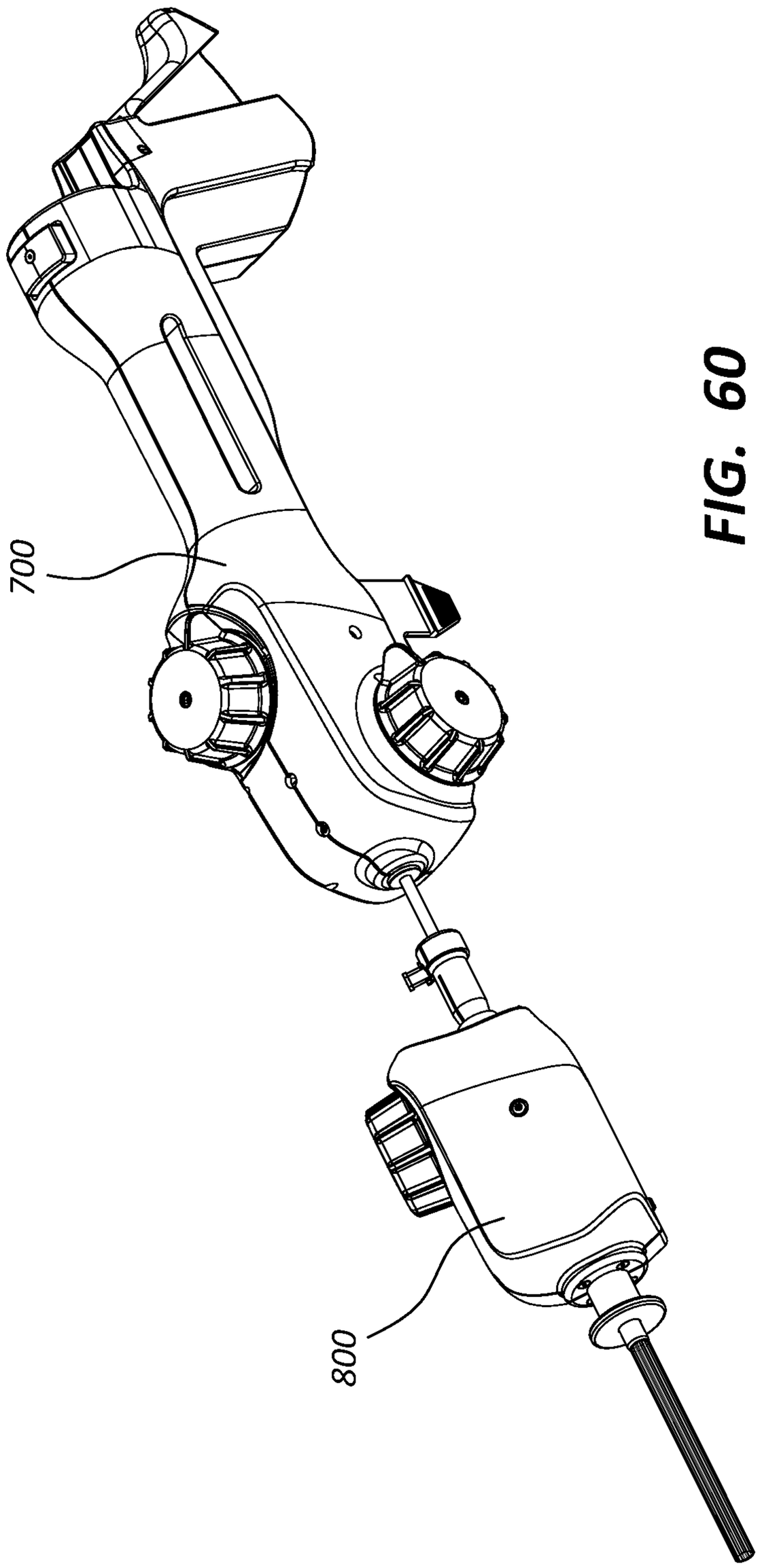


FIG. 60

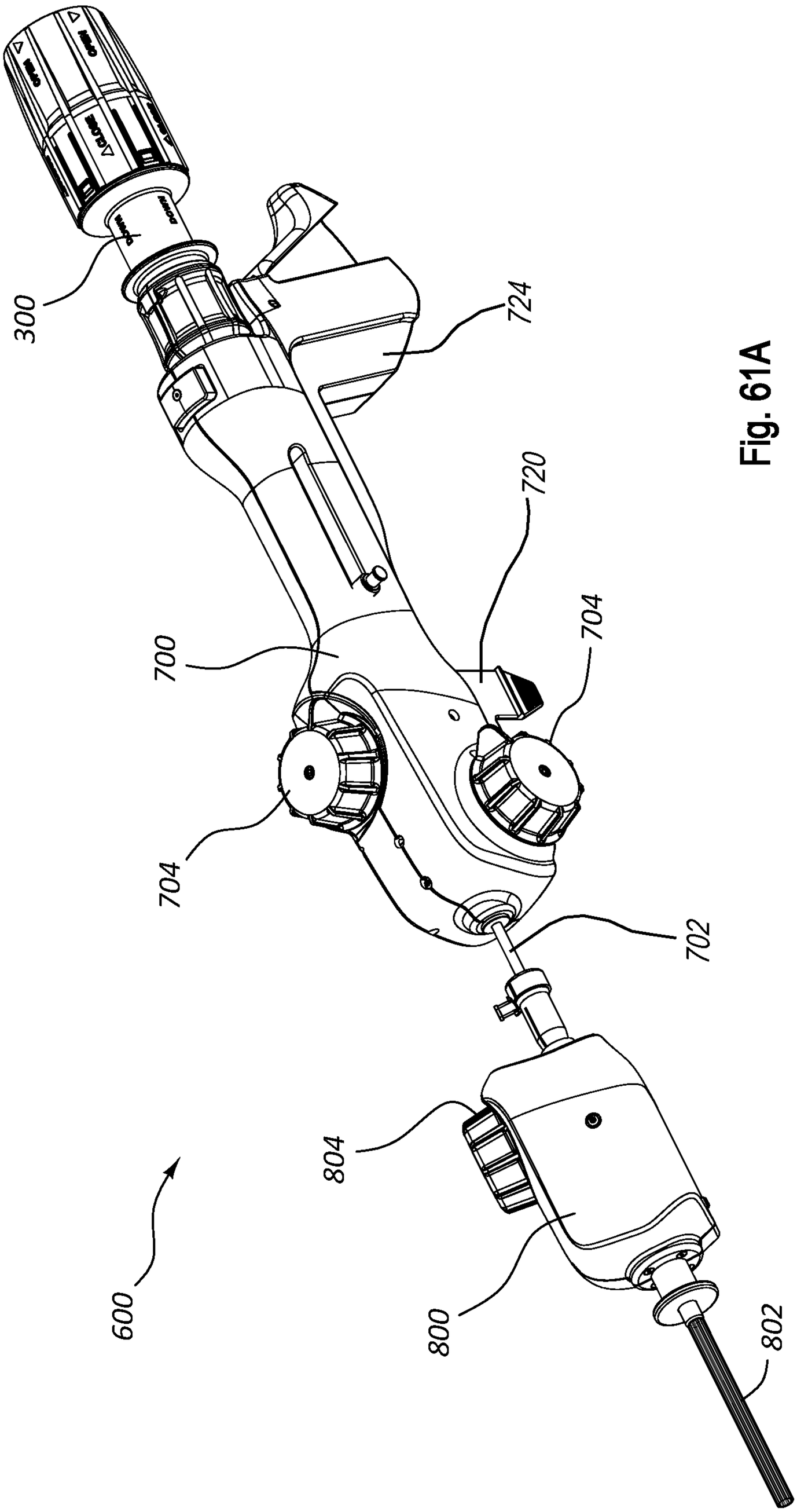


Fig. 61A

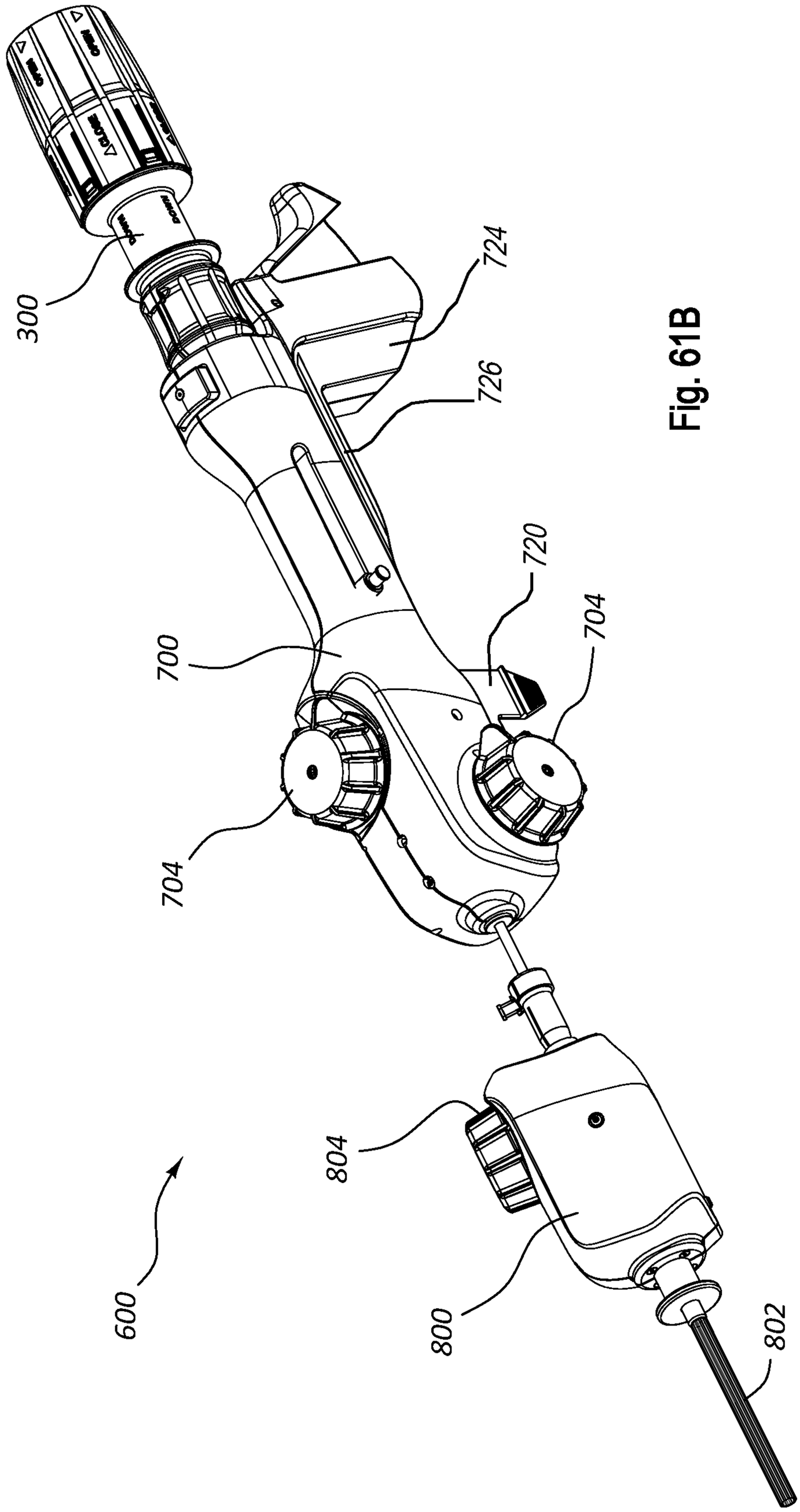


Fig. 61B

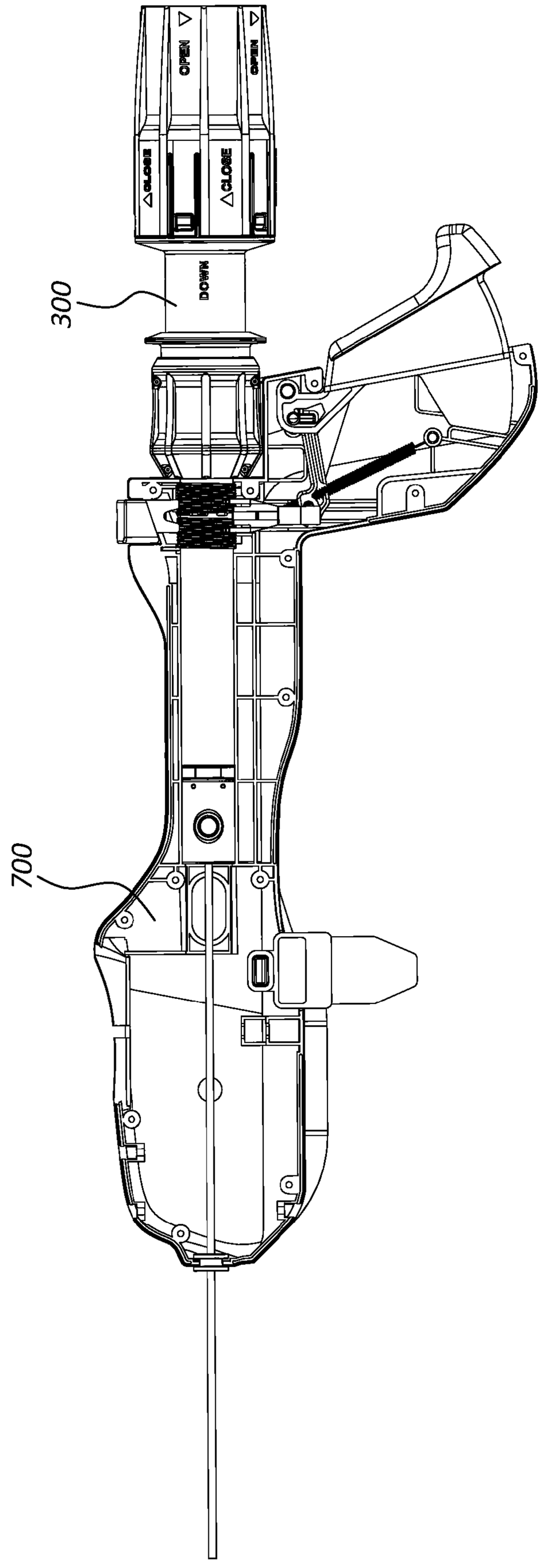
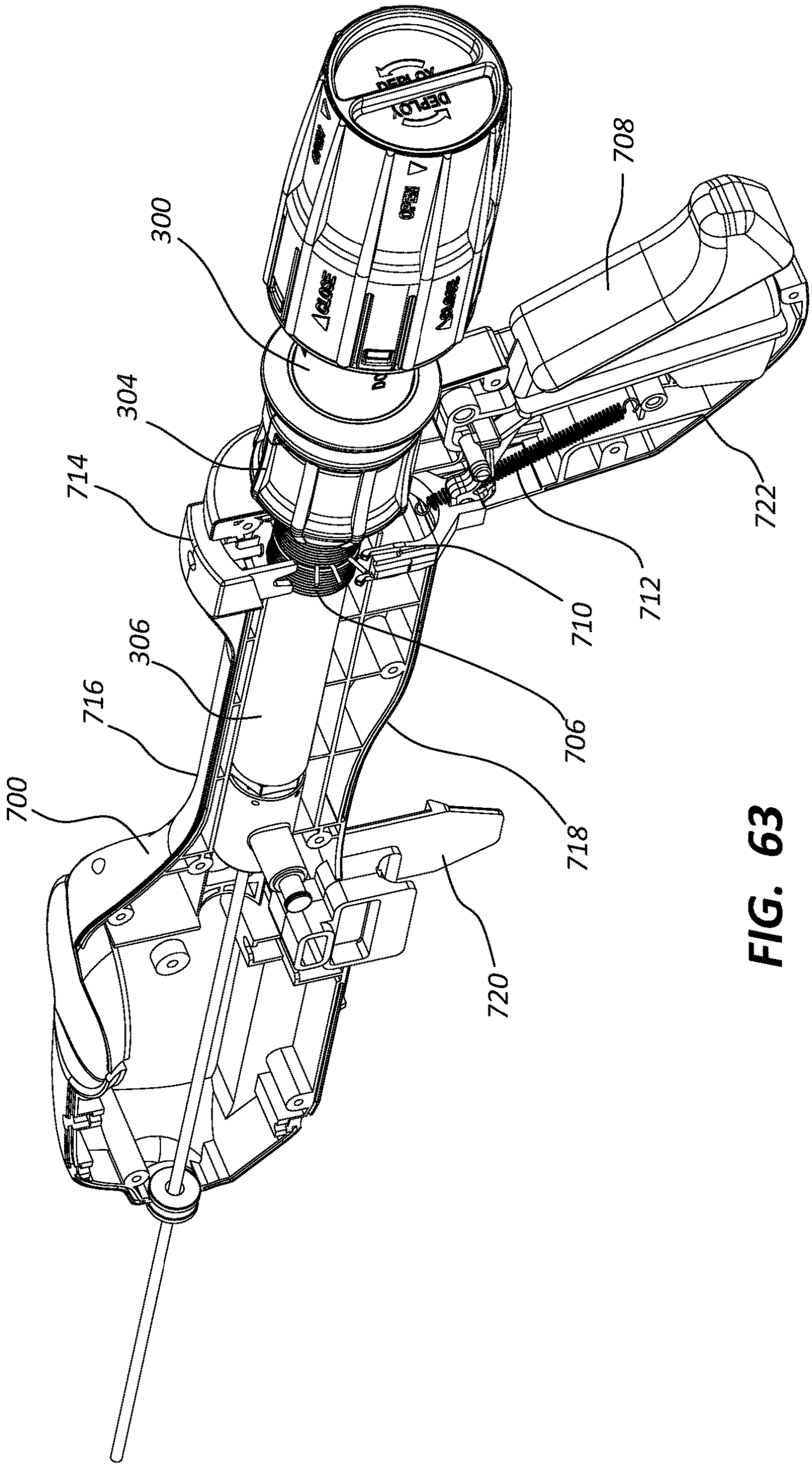


FIG. 62


DEPLOY
DEPLOY
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CLOSE
CLOSE
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FIG. 63

DELIVERY CATHETER HANDLE AND METHODS OF USE

CROSS-REFERENCE TO RELATED APPLICATIONS

N/A

BACKGROUND

1. The Field of the Disclosure

The present disclosure relates generally to medical methods, devices, and systems. In particular, the present disclosure relates to methods, devices, and systems for the endovascular or minimally invasive surgical repair of the atrioventricular valves of the heart, particularly the mitral valve.

2. The Relevant Technology

Mitral valve regurgitation is characterized by retrograde flow from the left ventricle of a heart through an incompetent mitral valve into the left atrium. During a normal cycle of heart contraction (systole), the mitral valve acts as a check valve to prevent flow of oxygenated blood back into the left atrium. In this way, the oxygenated blood is pumped into the aorta through the aortic valve. Regurgitation of the valve can significantly decrease the pumping efficiency of the heart, placing the patient at risk of severe, progressive heart failure.

Mitral valve regurgitation can result from a number of different mechanical defects in the mitral valve. The valve leaflets, the valve chordae which connect the leaflets to the papillary muscles, or the papillary muscles themselves may be damaged or otherwise dysfunctional. Commonly, the valve annulus may be damaged, dilated, or weakened limiting the ability of the mitral valve to close adequately against the high pressures of the left ventricle.

The most common treatments for mitral valve regurgitation rely on valve replacement or strengthening of the valve annulus by implanting a mechanical support ring or other structure. The latter is generally referred to as valve annuloplasty. A recent technique for mitral valve repair which relies on suturing adjacent segments of the opposed valve leaflets together is referred to as the "bow-tie" or "edge-to-edge" technique. While all these techniques can be very effective, they usually rely on open heart surgery where the patient's chest is opened, typically via a sternotomy, and the patient placed on cardiopulmonary bypass. The need to both open the chest and place the patient on bypass is traumatic and has associated morbidity.

For these reasons, it would be desirable to provide alternative and additional methods, devices, and systems for performing the repair of mitral and other cardiac valves, particularly the tricuspid valve which is the other atrioventricular valve. Such methods, devices, and systems should preferably not require open chest access and be capable of being performed endovascularly, i.e., using devices which are advanced to the heart from a point in the patient's vasculature remote from the heart. Still more preferably, the methods, devices, and systems should not require that the heart be bypassed, although the methods, devices, and systems should be useful with patients who are bypassed and/or whose heart may be temporarily stopped by drugs or other techniques. At least some of these objectives will be met by the inventions described hereinbelow.

BRIEF SUMMARY

Certain embodiments of the present disclosure relate to a medical delivery assembly, including: a housing; a delivery device disposed at least partially within the housing; a lock configured to releasably secure the delivery device relative to the housing when in a locked configuration, and to allow translation of the delivery device within the housing when in an unlocked configuration; a lock actuator configured to engage with the lock to move the lock from the locked configuration toward the unlocked configuration; and a handle coupled to the lock actuator, the handle being configured to move the lock actuator to engage with the lock upon the handle being moved from a default position toward a depressed position.

Certain embodiments relate to a delivery system including: a housing; a delivery device disposed at least partially within the housing; a lock configured to releasably secure the delivery device relative to the housing when in a locked configuration, and to allow translation of the delivery device within the housing when in an unlocked configuration; a lock actuator configured to engage with the lock to move the lock from the locked configuration toward the unlocked configuration; and a handle coupled to the lock actuator, the handle being configured to move the lock actuator to engage with the lock upon the handle being moved from a default position toward a depressed position; a sleeve having a proximal end coupled to the housing; and a catheter having a proximal end coupled to the delivery device, the catheter extending distally from the delivery device through a lumen of the sleeve; wherein depression of the handle allows the delivery device to be translated within the housing so as to translate the catheter within the sleeve.

Certain embodiments of the present disclosure relate to a medical delivery system, including: a delivery assembly having a housing, a delivery device disposed at least partially within the housing, a lock configured to releasably secure the delivery device relative to the housing when in a locked configuration, and to allow translation of the delivery device within the housing when in an unlocked configuration, a lock actuator configured to engage with the lock to move the lock from the locked configuration toward the unlocked configuration, and a handle coupled to the lock actuator, the handle being configured to move the lock actuator to engage with the lock upon the handle being moved from a default position toward a depressed position; a sleeve having a proximal end coupled to the housing; and a catheter having a proximal end coupled to the delivery device, the catheter extending distally from the delivery device through a lumen of the sleeve; wherein depression of the handle allows the delivery device to be translated within the housing so as to translate the catheter within the sleeve.

Certain embodiments relate to a method of positioning a catheter at a target area, the method including: positioning a distal end of a sleeve at a target area, the sleeve having a proximal end coupled to a delivery assembly, the delivery assembly including a housing coupled to the sleeve, a delivery device disposed at least partially within the housing, a lock configured to releasably secure the delivery device relative to the housing when in a locked configuration, and to allow translation of the delivery device within the housing when in an unlocked configuration, a lock actuator configured to engage with the lock to move the lock from the locked configuration toward the unlocked configuration, and a handle coupled to the lock actuator, the handle being configured to move the lock actuator to engage with the lock upon the handle being moved from a default position toward a depressed position; depressing the handle to allow the delivery device to be translated within the housing; and translating the delivery device within the housing so as to translate the catheter within the sleeve.

Certain embodiments relate to a deployment handle for staged deployment of an implantable device from a delivery device, the deployment handle including: a lock cap removably attached to a housing lid; a lock line assembly configured to lock the implantable device by moving from an unlocked position toward a locked position, the lock line assembly including a lock tab configured to lodge within a lock slot disposed on the housing lid so as to hold the lock line assembly in the unlocked position; and an actuator handle at least partially enclosed by the lock cap, the actuator handle being configured to provide decoupling of the implantable device from the delivery device upon actuation of the actuator handle; wherein the lock cap is configured to prevent access to the actuator handle prior to removal, and is configured to engage with the lock tab upon removal of the lock cap so as to dislodge the lock tab to allow the lock line assembly to move toward the locked position.

Certain embodiments are directed to a delivery system for staged deployment of an implantable device at a target area, the delivery system including: a delivery catheter having a proximal end and a distal end; an adjustable implantable device coupled to the distal end of the delivery catheter; and a delivery device coupled to the proximal end of the delivery catheter, the delivery device including a deployment handle and one or more lock lines extending from the deployment handle through the catheter to the implantable device, the one or more lock lines being configured to engage with the implantable device to allow locking of the implantable device, the deployment handle including: a lock cap removably attached to a housing lid; a lock line assembly coupled to the one or more lock lines and configured to lock the implantable device by moving from an unlocked position toward a locked position, the lock line assembly including a lock tab configured to lodge within a lock slot disposed on the housing lid so as to hold the lock line assembly in the unlocked position; and an actuator handle at least partially enclosed by the lock cap, the actuator handle being configured to provide decoupling of the implantable device from the delivery device upon actuation of the actuator handle; wherein the lock cap is configured to prevent access to the actuator handle prior to removal, and is configured to engage with the lock tab upon removal of the lock cap so as to dislodge the lock tab to allow the lock line assembly to move toward the locked position to lock the implantable device.

Certain embodiments relate to a delivery system for staged deployment of an implantable device at a target area, the delivery system including: a catheter having a proximal end and a distal end; an adjustable implantation device coupled to the distal end of the catheter; and a delivery device coupled to the proximal end of the catheter, the delivery device including a deployment handle and one or more lock lines extending from the deployment handle through the catheter to the implantation device, the one or more lock lines being configured to engage with the implantation device to allow locking of the implantation device, the deployment handle including a lock cap removably attached to a housing lid, a lock line assembly coupled to the one or more lock lines and configured to lock the implantation device by moving from an unlocked position toward a locked position, the lock line assembly including a lock tab configured to lodge within a lock slot disposed on the housing lid so as to hold the lock line assembly in the unlocked position, and an actuator handle at least partially enclosed by the lock cap, the actuator handle being configured to provide decoupling of the implantation device from the delivery device upon actuation of the actuator handle; wherein the lock cap is configured to prevent access to the actuator handle prior to removal, and is configured to engage with the lock tab upon removal of the lock cap so as to dislodge the lock tab to allow the lock line assembly to move toward the locked position to lock the implantation device.

Certain embodiments relate to a method of deploying an implantation device at a target area, the method including: positioning the implantation device at a target area, the implantation device being coupled to a distal end of a delivery catheter and a deployment handle being coupled to a proximal end of the delivery catheter, wherein one or more lock lines extend from the deployment handle through the catheter to engage with the implantation device such that application or release of tension in the one or more lock lines provides locking of the implantation device, the deployment handle including a lock cap removably attached to a housing lid, a lock line assembly coupled to the one or more lock lines and configured to apply or release tension in the one or more lock lines by moving from an unlocked position toward a locked position, the lock line assembly including a lock tab configured to lodge within a slot disposed on the housing lid so as to hold the lock line assembly in the unlocked position, and an actuator handle at least partially enclosed by the lock cap, the actuator handle being configured to provide decoupling of the implantation device from the delivery catheter upon actuation of the actuator handle, wherein the lock cap is configured to prevent access to the actuator handle prior to removal, and is configured to engage with the lock tab upon removal of the lock cap so as to dislodge the lock tab to allow the lock line assembly to move toward the locked position; orienting the implantation device in a desired configuration; and removing the lock cap to lock the implantation device.

Certain embodiments relate to a control line assembly for use with a medical delivery device, the control line assembly including: a shuttle slidably disposed within a shaft; a collar configured to be translatable along the shaft, the collar configured to engage with the shuttle upon translation of the collar such that translation of the collar along the shaft causes translation of the shuttle within the shaft; and a hub coupled to the shuttle and configured to receive and secure one or more control lines extending distally from the hub such that translation of the shuttle within the shaft applies or releases tension in the one or more control lines.

Certain embodiments are directed to a medical device delivery system, including: a delivery device, the delivery device including a control line assembly, a catheter, and one or more control lines extending from the control line assembly through the catheter, the control line assembly including: a shuttle slidably disposed within a shaft; a hub coupled to the shuttle and configured to receive and secure the one or more control lines; and a collar configured to be translatable along the shaft, the collar configured to engage with the shuttle upon translation of the collar such that translation of the collar along the shaft causes translation of the shuttle within the shaft so as to apply or release tension in the one or more control lines; and an implantable device attached to a distal end of the catheter, the one or more control lines extending through the catheter and engaging with the implantable device such that translation of the collar adjusts the implantable device.

Certain embodiments relate to a medical device delivery system, including: a delivery device, the delivery device including a control line assembly, a catheter, and one or more control lines extending from the control line assembly through the catheter, the control line assembly including a shuttle slidably disposed within a shaft, a hub coupled to the

shuttle and configured to receive and secure the one or more control lines, and a collar configured to be translatable along the shaft, the collar configured to engage with the shuttle upon translation of the collar such that translation of the collar along the shaft causes translation of the shuttle within the shaft so as to apply or release tension in the one or more control lines; and an implantable device attached to a distal end of the catheter, the one or more control lines extending through the catheter and engaging with the implantable device such that translation of the collar adjusts the implantable device.

Certain embodiments relate to a method of actuating an implantable device at a target area, the method including: positioning an implantable device at a target area, the implantable device being coupled to a distal end of a delivery catheter and a control line assembly being coupled to a proximal end of the delivery catheter, wherein one or more control lines extend from the control line assembly through the catheter to engage with the implantable device such that application or release of tension in the one or more control lines actuates the implantable device, the control line assembly including a shuttle slidably disposed within a shaft, a hub coupled to the shuttle and configured to receive and secure the one or more control lines, and a collar configured to be translatable along the shaft, the collar configured to engage with the shuttle upon translation of the collar such that translation of the collar along the shaft causes translation of the shuttle within the shaft so as to apply or release tension in the one or more control lines; and actuating the implantable device by translating the collar along the shaft.

Certain embodiments relate to a control line assembly for use with a medical delivery device, the control line assembly including: a carriage slidably disposed within a shaft; a hub coupled to the carriage and configured to receive and secure one or more control lines extending distally from the carriage such that translation of the carriage within the shaft applies or releases tension in the one or more control lines; a housing lid disposed on a proximal side of the carriage; and a lock tab extending from the carriage toward the housing lid, the housing lid including a slot configured in size and shape to allow passage of the lock tab through the slot and to allow the lock tab to be lodged in the slot so as to restrict translation of the carriage within the shaft.

Certain embodiments are directed to a medical device delivery system, including: a delivery device, the delivery device including a control line assembly, a catheter, and one or more control lines extending from the control line assembly through the catheter, the control line assembly including: a carriage slidably disposed within a shaft; a hub coupled to the carriage and configured to receive and secure the one or more control lines such that translation of the carriage within the shaft applies or releases tension in the one or more control lines; a housing lid disposed on a proximal side of the carriage; and a lock tab extending from the carriage toward the housing lid, the housing lid including a slot configured in size and shape to allow passage of the lock tab through the slot and to allow the lock tab to be lodged in the slot so as to restrict translation of the carriage within the shaft; and an implantable device attached to a distal end of the catheter, the one or more control lines extending through the catheter to the implantable device to provide control of the implantable device, wherein lodging of the lock tab within the slot restricts actuation of the implantable device.

Certain embodiments relate to a medical device delivery system, including: a delivery device, the delivery device including a control line assembly, a catheter, and one or more control lines extending from the control line assembly through the catheter, the control line assembly including a carriage slidably disposed within a shaft, a hub coupled to the carriage and configured to receive and secure the one or more control lines such that translation of the carriage within the shaft applies or releases tension in the one or more control lines, a housing lid disposed on a proximal side of the carriage, and a lock tab extending from the carriage toward the housing lid, the housing lid including a slot configured in size and shape to allow passage of the lock tab through the slot and to allow the lock tab to be lodged in the slot so as to restrict translation of the carriage within the shaft; and an implantable device attached to a distal end of the catheter, the one or more control lines extending through the catheter to the implantable device to provide control of the implantable device, wherein lodging of the lock tab within the slot restricts actuation of the implantable device.

Certain embodiments relate to a method of locking an implantable device in a desired configuration at a target area, the method including: positioning an implantable device at a target area, the implantable device being coupled to a distal end of a delivery catheter and a control line assembly being coupled to a proximal end of the delivery catheter, wherein one or more control lines extend from the control line assembly through the catheter to engage with the implantable device such that application or release of tension in the one or more control lines actuates the implantable device, the control line assembly including a carriage slidably disposed within a shaft, a hub coupled to the carriage and configured to receive and secure the one or more control lines such that translation of the carriage within the shaft applies or releases tension in the one or more control lines, a housing lid disposed on a proximal side of the carriage, and a lock tab extending from the carriage toward the housing lid, the housing lid including a slot configured in size and shape to allow passage of the lock tab through the slot and to allow the lock tab to be lodged in the slot so as to restrict translation of the carriage within the shaft; orienting the implantable device in a desired configuration; and locking the implantable device by lodging the lock tab within the slot to prevent actuation of the implantable device.

Certain embodiments relate to a fluid management system for use with a medical delivery device, the fluid management system including: a flush body, the flush body including an opening, a catheter outlet, and a fluid inlet configured to receive a fluid into an interior space of the flush body; a grommet at least partially housed within the flush body, the grommet having an interior lumen and being configured to be in fluid communication with the interior space such that fluid can pass from the interior space into the interior lumen; and a conducting assembly disposed at the opening, the conducting assembly configured to receive one or more components of the delivery device and direct the one or more components into the interior lumen; wherein the grommet is configured to be couplable to a catheter extending through the catheter outlet so as to allow the catheter to receive the fluid and the one or more components from the interior lumen and transport the fluid and the one or more components through the catheter outlet.

Certain embodiments are directed to a medical device delivery system, including: a delivery device, the delivery device including a fluid management system and a delivery catheter coupled to the fluid management system, the fluid management system including: a flush body, the flush body including an opening, a catheter outlet, and a fluid inlet configured to receive a fluid into an interior space of the flush body; a grommet at least partially housed within the

flush body, the grommet having an interior lumen and being configured to be in fluid communication with the interior space such that fluid can pass from the interior space into the interior lumen; and a conducting assembly disposed at the opening, the conducting assembly configured to receive one or more components of the delivery device and direct the one or more components into the interior lumen; wherein a proximal end of the delivery catheter is coupled to the grommet so as to allow the delivery catheter to receive the fluid and the one or more components from the interior lumen and transport the fluid and the one or more components through the catheter outlet; and an implantable device attached to a distal end of the delivery catheter, the delivery catheter being configured to transport the fluid and the one or more components from the fluid management system to the implantable device.

Certain embodiments relate to a medical device delivery system, including: a delivery device, the delivery device including a fluid management system and a delivery catheter coupled to the fluid management system, the fluid management system including a flush body, the flush body including an opening, a catheter outlet, and a fluid inlet configured to receive a fluid into an interior space of the flush body, a grommet at least partially housed within the flush body, the grommet having an interior lumen and being configured to be in fluid communication with the interior space such that fluid can pass from the interior space into the interior lumen, and a conducting assembly disposed at the opening, the conducting assembly configured to receive one or more components of the delivery device and direct the one or more components into the interior lumen, wherein a proximal end of the delivery catheter is coupled to the grommet so as to allow the delivery catheter to receive the fluid and the one or more components from the interior lumen and transport the fluid and the one or more components through the catheter outlet; and an implantable device attached to a distal end of the delivery catheter, the delivery catheter being configured to transport the fluid and the one or more components from the fluid management system to the implantable device.

Certain embodiments relate to a method of directing fluid in a medical delivery device, the method including: injecting a fluid into the medical delivery device, the medical delivery device including a fluid management system and a catheter coupled to the fluid management system, the fluid management system including a flush body, the flush body including an opening, a catheter outlet, and a fluid inlet configured to receive a fluid into an interior space of the flush body, a grommet at least partially housed within the flush body, the grommet having an interior lumen and being configured to be in fluid communication with the interior space such that fluid can pass from the interior space into the interior lumen, a conducting assembly disposed at the opening, the conducting assembly configured to receive one or more components of the delivery device and direct the one or more components into the interior lumen, wherein a proximal end of the catheter passes through the catheter outlet and is coupled to the grommet so as to allow the catheter to receive the fluid and the one or more components from the interior lumen; and transporting the fluid through the catheter to an implantable device at a distal end of the catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to describe the manner in which the above-recited and other features of the disclosure can be obtained, a more particular description will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. For better understanding, the like elements have been designated by like reference numbers throughout the various accompanying figures. While some of the drawings may be schematic or exaggerated representations of concepts, at least some of the drawings may be drawn to scale. Understanding that the drawings depict some example embodiments, the embodiments will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

FIG. **1** illustrates cardiac physiology;

FIG. **2** illustrates free edges of leaflets in normal coaptation, and FIG. **3** illustrates the free edges in regurgitative coaptation;

FIGS. **4-6** illustrate an embodiment of grasping heart valve leaflets using a fixation device;

FIG. **7** illustrates a position of the fixation device in a desired orientation relative to the leaflets;

FIGS. **8-11** illustrate embodiments of a coupling mechanism configured to couple a fixation device to an actuator rod;

FIGS. **12-27** illustrate an embodiment of a fixation device in various positions;

FIGS. **28-31** illustrate an embodiment of a fixation device including a locking mechanism;

FIG. **32** illustrates a delivery device according to the present disclosure;

FIGS. **33-34** illustrate a fixation device that is coupleable to a delivery catheter;

FIGS. **35-37** illustrate various arrangements of lock lines engaging a locking mechanism;

FIGS. **38-39** illustrate various arrangements of gripper lines engaging grippers;

FIGS. **40-41** illustrate various components of a fluid management system according to the present disclosure;

FIGS. **42-43** illustrate various components of a gripper line management system according to the present disclosure;

FIGS. **44-45** illustrate various components of a lock line management system according to the present disclosure;

FIG. **46** illustrates gripper lines attached to a gripper line shuttle;

FIGS. **47-49** illustrate various components of an actuator assembly according to the present disclosure;

FIGS. **50-54** illustrate an embodiment of a deployment handle configured to provide staged deployment of a fixation device;

FIGS. **55-59** illustrate another embodiment of a deployment handle configured to provide staged deployment of a fixation device;

FIGS. **60** and **61**A-**61**B illustrate various components of a delivery system according to the present disclosure; and

FIGS. **62-63** illustrate an embodiment of a delivery system handle.

DETAILED DESCRIPTION

I. Cardiac Physiology

The left ventricle LV of a normal heart H in systole is illustrated in FIG. **1**. The left ventricle LV is contracting and blood flows outwardly through the tricuspid (aortic) valve AV in the direction of the arrows. Back flow of blood or "regurgitation" through the mitral valve MV is prevented since the mitral valve is configured as a "check valve" which prevents back flow when pressure in the left ventricle is higher than that in the left atrium LA. The mitral valve MV comprises a pair of leaflets having free edges FE which meet

evenly to close, as illustrated in FIG. **1**. The opposite ends of the leaflets LF are attached to the surrounding heart structure along an annular region referred to as the annulus AN. The free edges FE of the leaflets LF are secured to the lower portions of the left ventricle LV through chordae tendinae CT (referred to hereinafter as the chordae) which include plurality of branching tendons secured over the lower surfaces of each of the valve leaflets LF. The chordae CT in turn, are attached to the papillary muscles PM which extend upwardly from the lower portions of the left ventricle and intraventricular septum IVS.

A number of structural defects in the heart can cause mitral valve regurgitation. Regurgitation occurs when the valve leaflets do not close properly allowing leakage from the ventricle into the atrium. As shown in FIG. **2**, the free edges of the anterior and posterior leaflets normally meet along a line of coaptation C. An example of a defect causing regurgitation is shown in FIG. **3**. Here an enlargement of the heart causes the mitral annulus to become enlarged, making it impossible for the free edges FE to meet during systole. This results in a gap G which allows blood to leak through the valve during ventricular systole. Ruptured or elongated chordae can also cause a valve leaflet to prolapse since inadequate tension is transmitted to the leaflet via the chordae. While the other leaflet maintains a normal profile, the two valve leaflets do not properly meet and leakage from the left ventricle into the left atrium will occur. Such regurgitation can also occur in patients who have suffered ischemic heart disease where the left ventricle does not contract sufficiently to effect proper closure.

II. General Overview

The present disclosure provides methods and devices for grasping, approximating and fixating tissues, such as heart valve leaflets, to treat cardiac valve regurgitation, particularly mitral valve regurgitation. The present disclosure provides methods and devices for delivering an implantable device to a treatment area, such as delivering an implantable heart valve device (e.g., an implantable mitral valve device) to a target heart valve. These and other applications can include, for example, implant, repair, and/or fixation procedures related to functional mitral valve regurgitation or implant, repair, and/or fixation procedures related to the tricuspid valve, pulmonary valve, aortic valve, or other related heart tissues. The present disclosure also provides features that allow repositioning and removal of the implantable device if so desired, particularly in areas where removal may be hindered by anatomical features such as chordae CT. Such removal would allow the surgeon to reapproach the valve in a new manner if so desired.

Grasping can be atraumatic. By atraumatic, it is meant that the devices and methods of the invention may be applied to the valve leaflets and then removed without causing any significant clinical impairment of leaflet (or other tissue) structure or function. For example, the leaflets and valve of a treated mitral valve can continue to function substantially the same or better as before embodiments of the present disclosure have been applied. Thus, some minor penetration or denting of the leaflets may occur using embodiments of the present disclosure while still meeting the definition of "atraumatic." This enables the devices of the present disclosure to be applied to a diseased valve and, if desired, removed or repositioned without having negatively affected valve function. In addition, it will be understood that in some cases it may be necessary or desirable to pierce or otherwise permanently affect the leaflets during grasping, fixing, or both. In some of these cases, grasping and fixation may be accomplished by a single device.

The systems, devices and methods of the present disclosure rely upon the use of an interventional tool (which, in some embodiments, can also function as an implantable device) that is positioned near a desired treatment site and used to grasp the target tissue. In endovascular applications, the interventional tool is typically an interventional catheter. In surgical applications, the interventional tool is typically an interventional instrument. In some embodiments, fixation of the grasped tissue is accomplished by maintaining grasping with a portion of the interventional tool which is left behind as an implant. While embodiments of the disclosure may have a variety of applications for implantation, tissue approximation, and/or fixation throughout the body, it is particularly well adapted for the repair of valves, especially cardiac valves such as the mitral valve.

Referring to FIG. **4**, an interventional tool **10**, having a delivery assembly, such as a shaft **12**, and an implantable device **14**, is illustrated having approached the mitral valve MV from the atrial side and grasped the leaflets LF. The mitral valve may be accessed either surgically or by using endovascular techniques, and/or either by a retrograde approach through the ventricle or by an antegrade approach through the atrium, as described above. For illustration purposes, an antegrade approach is described.

The implantable device **14** may be releasably attached to the shaft **12** of the interventional tool **10** at its distal end. When describing the devices of the present disclosure herein, "proximal" shall mean the direction toward the end of the device to be manipulated by an operator outside the patient's body, and "distal" shall mean the direction toward the working end of the device that is positioned at the treatment site and away from the operator. With respect to the mitral valve, proximal shall refer to the atrial or upstream side of the valve leaflets and distal shall refer to the ventricular or downstream side of the valve leaflets. As described herein, an implantable device, such as implantable device **14**, may include an implantable device and/or a fixation device, such as a valve repair device (e.g., a MITRA-CLIP®), a valve replacement device, or another implantable device.

The implantable device **14** can include gripping elements **16** and distal elements **18** which can protrude radially outward and may be positionable on opposite sides of the leaflets LF as shown so as to be able to capture or retain the leaflets therebetween. The gripping elements **16** may be formed of cobalt chromium, a nickel-titanium alloy, or stainless steel, and the distal elements **18** may be formed of cobalt chromium or stainless steel; however, any suitable materials may be used (e.g., polymers, other metals, and/or biocompatible materials).

The gripping elements **16** may be formed as one integral piece, referred to herein as a "gripper." In other embodiments, the gripping elements may be separately formed and/or otherwise decoupled. The implantable device **14** may be coupleable to the shaft **12** by a coupling mechanism **17**. The coupling mechanism **17** can allow the implantable device **14** to detach and be left behind as an implant to hold the leaflets together in the coapted position.

In some situations, it may be desired to reposition and/or remove the implantable device **14** after the gripper elements **16**, distal elements **18**, or both have been deployed to capture the leaflets LF. Such repositioning and/or removal may be desired for a variety of reasons, such as to reapproach the valve in an attempt to achieve better valve function, more optimal positioning of the device **14** on the leaflets, better

purchase on the leaflets, to detangle the device **14** from surrounding tissue (such as chordae), to exchange the device **14** with one having a different design, and/or to abort the fixation procedure, for example.

To facilitate repositioning or removal of the implantable device **14** the distal elements **18** can be releasable and optionally invertible to a configuration suitable for withdrawal of the device **14** from the valve without tangling, interfering with, and/or damaging the chordae, leaflets and/or other tissue. FIG. **5** illustrates inversion wherein the distal elements **18** are moveable in the direction of arrows **40** to an inverted position. The gripper elements **16** may be raised, if desired. In the inverted position, the device **14** may be repositioned to a desired orientation wherein the distal elements **18** may then be reverted to a grasping position against the leaflets as in FIG. **4**. Alternatively, the implantable device **14** may be withdrawn (indicated by arrow **42**) from the target area as shown in FIG. **6**. Such inversion can reduce trauma to the leaflets and can minimize any entanglement of the device with surrounding tissues. Once the implantable device **14** has been withdrawn through the valve leaflets, the gripper elements **16** and distal elements **18** may be moved to a closed position or configuration suitable for removal from the body or for reinsertion through the mitral valve.

FIG. **7** illustrates the position of the implantable device **14** in one desired orientation in relation to the leaflets LF. This is a short-axis view of the mitral valve MV from the atrial side, therefore, the gripper elements **16** are shown in solid line and the distal elements **18** are hidden from view and shown in dashed line. As shown, the gripper elements **16** and distal elements **18** can be positioned to be substantially perpendicular to the line of coaptation C. The implantable device **14** may be moved roughly along the line of coaptation to the location of regurgitation. The leaflets LF can be held in place so that during diastole, as shown in FIG. **7**, the leaflets LF remain in position between the gripper elements **16** and the distal elements **18** surrounded by openings O which result from the diastolic pressure gradient. Advantageously, leaflets LF can be coapted such that their proximal or upstream surfaces are facing each other in a vertical orientation, parallel to the direction of blood flow through mitral valve MV. The upstream surfaces may be brought together so as to be in contact with one another or may be held slightly apart, but will preferably be maintained in the vertical orientation in which the upstream surfaces face each other at the point of coaptation. This simulates the double orifice geometry of a standard surgical bow-tie repair.

Color Doppler echo can show if the regurgitation of the valve has been reduced. If the resulting mitral flow pattern is satisfactory, the leaflets may be fixed together in this orientation. If the resulting color Doppler image shows insufficient improvement in mitral regurgitation, the interventional tool **10** may be repositioned. This may be repeated until an optimal result is produced wherein the leaflets LF are held in place.

Once the leaflets are coapted in the desired arrangement, the implantable device **14** can be detached from the shaft **12** and left behind as an implant to hold the leaflets together in the coapted position. As mentioned previously, the implantable device **14** can be coupled to the shaft **12** by a coupling mechanism **17**. FIGS. **8-11** illustrate exemplary embodiments of such coupling mechanisms.

FIG. **8** shows an upper shaft **20** and a detachable lower shaft **22** which are interlocked at a joining line or mating surface **24**. The mating surface **24** may have any shape or curvature which will allow or facilitate interlocking and later detachment. A snuggly fitting outer sheath **26** may be positioned over the upper shaft **20** and lower shaft **22** to cover the mating surface **24**, as shown. FIG. **9** illustrates detachment of the lower shaft **22** from the upper shaft **20**. This may be achieved by retracting the outer sheath **26**, so that the mating surface **24** is exposed, which allows the upper shaft **20** and lower shaft **22** to separate.

FIGS. **10-11** illustrate another exemplary coupling mechanism. Here, upper shaft **500** is releasably coupled with lower shaft **506** with a detent mechanism **504**, **508**. The upper and lower shafts in this embodiment are generally tubular shaped although one of skill in the art will appreciate that other configurations are possible. The detent mechanism includes one or more spring arms **502** integrally formed on tubular upper shaft **500** and one or more receptacles **508** sized to receive the spring arms **502**. Tubular upper shaft **500** is integrally formed with one or more spring arms **502** having a flange-like engagement surface **504** at a distal end thereof. The spring arms **502** are preferably biased inwardly, i.e., toward the interior of the shaft **500**. Detachable tubular lower shaft **506** features one or more receptacles, here apertures **508** configured to receive and mate with the engagement surface **504** of the spring arm **502**. The apertures **508** may extend partially or all the way through the wall of the lower shaft **506**. A snuggly fitting rod **34** or inner member is inserted through the tubular shafts **500**, **506** outwardly deflecting the inwardly biased spring arm(s) **502** such that the engagement surface **504** is pushed into engagement with a corresponding receptacle **508** thereby preventing detachment of the upper shaft **500** from the lower shaft **506**. In FIGS. **10-11**, two spring arms **502** are illustrated; however, any number of spring arms may be used. Thus the invention should be understood to encompass an embodiment having a single spring arm **50** as well as an embodiment having three or more spring arms **502**.

FIG. **11** illustrates detachment of the lower shaft **506** from the upper shaft **500**. This is achieved by retracting the rod **34** to a position above the spring arm(s) **502** which allows the inwardly biased engagement surface **504** to disengage from the receptacle **508** allowing the shafts **500**, **506** to separate. The embodiment illustrated in FIGS. **10** and **11** depicts the spring arms **502** on the upper shaft **500** and the receptacle **508** on the lower shaft **506**. Though not illustrated, these features may be reversed with the spring arms **502** on the lower shaft **506** and the receptacle on the upper shaft **500**. In addition, while the spring arms **502** can be biased inwardly as described, the spring arms **502** alternatively can be biased outwardly and application of a proximal force on the shaft **500** is sufficient to release the engagement surface **504** from the receptacle **508**, optionally modified with curved or sloping interior corners to aid with disengagement. Other examples of coupling mechanisms are described and illustrated in U.S. Pat. No. 8,216,256, incorporated herein by reference for all purposes.

III. Implantable Device

A. Introduction and Placement of Implantable Device

The implantable device **14** may be delivered to the valve or other target tissue with the use of a medical delivery device configured to deliver an implantable device or other tissue treating device to a target area ("delivery device"). For endovascular applications, the delivery device can include a flexible delivery catheter which will be described in later sections. Such a catheter can include a shaft, having a proximal end and a distal end, and an implantable device releasably attached to the distal end. The shaft may be

elongate and flexible, suitable for intravascular introduction. Alternatively, the delivery device may include a shorter and less flexible interventional instrument which may be used for trans-thoracic surgical introduction through the wall of the heart, for example. An implantable device may be releasably coupleable with the delivery device as illustrated in FIG. **4**. The implantable device may have a variety of forms, a few embodiments of which will be described herein.

FIGS. **12-15** illustrate an embodiment of an implantable device **14** in various positions or configurations. FIG. **12** illustrates the implantable device **14** in a closed configuration suitable for delivery through a patient's vasculature and, in this example, through the mitral valve. The implantable device **14** may include a coupling member **19** which allows detachment of the implantable device **14** for implantation. In this example, the coupling member **19** is shown to include the lower shaft **22** and mating surface **24** of FIGS. **8-9**, and therefore the coupling member **19** can function similarly as described above. The implantable device **14** may also include a pair of opposed distal elements **18**, each distal element **18** having an engagement surface **50** facing inwardly toward the opposed distal element **18** in the closed configuration.

Distal elements **18** may include elongate arms **53**, each arm having a proximal end **52** rotatably connected to the coupling member **19**, and a free end **54**. Suitable connections for arms **53** to coupling member **19** include pins, living hinges, or other known rotational connection mechanisms. In the closed configuration of FIG. **12**, free ends can **54** point in a first direction such that the arms **53** and engagement surfaces **50** are nearly parallel to each other and to an axis **21**, and may be angled slightly inwardly toward each other. In some embodiments, when tissue is not present between arms **53**, the arms **53** may be closed until free ends **54** either touch each other or engage shaft **12** when implantable device **14** is attached thereto, thereby minimizing the profile of the implantable device **14** (e.g., for passage through a delivery device).

FIGS. **13-14** illustrate the implantable device **14** in an open position wherein the engagement surfaces **50** are disposed apart at a separation angle **56**. The separation angle **56** may be up to approximately 180 degrees, such as up to 90-180 degrees, and arms **53** may be disposed generally symmetrically relative to axis **21**. The arms **53** may be moveable to the open position by a variety of actuation mechanisms. For example, a plunger or actuator rod may be advanced through the coupling member **19**, as indicated by arrow **62**, so as to engage a spring or spring loaded actuation mechanism **58** which is attached to the distal elements **18**. By exerting a force against the actuation mechanism **58**, the distal elements **18** can be rotated relative to coupling member **19**. The distal elements **18** may be held in this open position by the actuator rod against the resistance provided by the spring of the actuation mechanism **58**, which biases the distal elements **18** toward the closed position of FIG. **12** when the distal elements **18** are less than 180 degrees apart. The spring loading of the actuation mechanism **58** can resist outward movement of the actuation mechanism **58** and/or can urge the device **14** towards the closed position.

In this embodiment, gripper elements **16** comprise resilient loop-shaped wire forms biased outwardly and attached to the coupling member **19** so as to be biased to an open position shown in FIG. **14**, but moveable rotationally inwardly when arms **53** are closed. The wire forms may be flexible enough to be rigidly attached to coupling member **19** and resiliently deflectable inwardly, or they may be attached by a rotational coupling such as a pin or living hinge. In use, leaflets LF (or other tissue) are positioned between the gripper elements **16** and distal elements **18**. Once the leaflets LF are positioned between the gripper elements **16** and distal elements **18**, the distal elements **18** may be closed, compressing the leaflets between engagement surfaces **50** and gripper elements **16**. Depending upon the thickness of the leaflets, the arrangements of the leaflets, the position of the implantable device on the leaflets, and other factors, the arms **53** may be maintained in the open position of FIG. **13**, moved to the fully closed position of FIG. **12**, or placed in any of various positions in between so as to coapt the leaflets LF and hold them in the desired position with the desired degree of force. In most cases, the implantable device **14** will remain in place as an implant following detachment from the delivery catheter.

In some situations, as described above, it may be desirable to reopen the implantable device **14** following initial placement. To reopen the device **14**, the actuator rod may be readvanced or reinserted through the coupling member **19** and readvanced to press against the actuation mechanism **58**, as previously indicated by arrow **62** in FIG. **13**. Again, such advancement applies a force against the actuation mechanism **58** in the manner described above, thus moving arms **53** outwardly to release force against leaflets and move engagement surfaces **50** away from gripper elements **16**. The leaflets are then free to move relative to implantable device **14**. The implantable device **14** may then be repositioned as desired and the actuator rod retracted to reclose the distal elements **18** to coapt the leaflets.

Under some circumstances, it may be desirable to withdraw the implantable device **14** back through the valve or completely from the patient following initial insertion through the valve. Should this be attempted with the clip in the closed or open positions illustrated in FIGS. **12-14**, there may be a risk that arms **53** could interfere or become entangled with the chordae, leaflets or other tissues. To avoid this, the fixation element **14** may be adapted for inversion of arms **53** so that free ends **54** point in a second direction, opposite to the first direction in which the free ends **54** pointed in the closed position, each arm **53** forming an obtuse angle relative to axis **21** as illustrated in FIG. **15**.

The arms **53** may be rotated so that the engagement surfaces **50** are disposed at a separation angle **56** of up to 360 degrees, or up to 270 degrees. This may be accomplished by exerting a force against actuation mechanism **58** with a push rod or plunger extending through coupling member **19** as described above. In this embodiment, once the distal elements **18** have rotated beyond 180 degrees apart, the spring loading of the actuation mechanism **58** can bias the distal elements **18** toward the inverted position. The spring loading of the actuation mechanism **58** can resist outward movement of the actuation mechanism **58** and can urge the device **14** towards the inverted position.

With arms **53** in the inverted position, engagement surfaces **50** can provide an atraumatic surface to deflect tissues as the implantable device is withdrawn. This allows the device to be retracted back through the valve annulus without risk of injury to valvular and other tissues. In some cases, once the implantable device **14** has been pulled back through the valve, it will be desirable to return the device to the closed position for withdrawal of the device from the body (either through the vasculature or through a surgical opening).

The embodiment illustrated in FIGS. **12-15** can be assembled from separate components composed of biocompatible materials. The components may be formed from the

same or different materials, including but not limited to stainless steel or other metals, Elgiloy®, nickel-titanium alloy, titanium, tantalum, metal alloys, or polymers. Additionally, some or all of these components may be made of bioabsorbable materials that can be absorbed by surrounding tissues or can dissolve into the bloodstream following implantation. It has been found that in mitral valve repair applications the implantable devices of the present disclosure are completely surrounded by tissue within a few months of implantation, after which the devices could dissolve or be absorbed without negative impact to the repair.

FIG. **16** illustrates an embodiment of an implantable device **14**. Here, the implantable device **14** is shown coupled to a shaft **12** to form an interventional tool **10**. The implantable device **14** may include a coupling member **19** and a pair of opposed distal elements **18**. The distal elements **18** can comprise elongate arms **53**, each arm having a proximal end **52** rotatably connected to the coupling member **19** and a free end **54**. The free ends **54** can have a rounded shape to minimize interference with and trauma to surrounding tissue structures. In some embodiments, each free end **54** defines a curvature about two axes, one being an axis **66** perpendicular to longitudinal axis of arms **53**. The engagement surfaces **50** can have a cupped or concave shape to surface area in contact with tissue and to assist in grasping and holding the valve leaflets. This further allows arms **53** to nest around the shaft **12** in the closed position to minimize the profile of the device.

In some embodiments, arms **53** are at least partially cupped or curved inwardly about their longitudinal axes **66**. In some embodiments, each free end **54** defines a curvature about an axis **67** perpendicular to axis **66** or the longitudinal axis of arms **53**. This curvature is a reverse curvature along the most distal portion of the free end **54**. The longitudinal edges of the free ends **54** may flare outwardly. The reverse curvature and/or flaring can minimize trauma to the tissue engaged therewith.

In some embodiments suitable for mitral valve repair, the transverse width across engagement surfaces **50** (which determines the width of tissue engaged) can be at least about 2 mm, such as 3-10 mm or about 4-6 mm. In some situations, a wider engagement is desired wherein the engagement surfaces **50** can be larger, for example about 2 cm. In some embodiments, multiple implantable devices are used adjacent to each other. Arms **53** and engagement surfaces **50** can be configured to engage a length of tissue of about 4-10 mm, and preferably about 6-8 mm along the longitudinal axis of arms **53**. Arms **53** can include a plurality of openings to enhance grip and to promote tissue ingrowth following implantation.

The valve leaflets can be grasped between the distal elements **18** and gripper elements **16**. In some embodiments, the gripper elements **16** can be flexible, resilient, and cantilevered from coupling member **19**. The gripper elements **16** can be resiliently biased toward the distal elements **18**. Each gripper element **16** can be shaped and positioned to be at least partially recessed within the concavity of the distal element **18** when no tissue is present. When the implantable device **14** is in the open position, the gripper elements **16** can be shaped such that each gripper element **16** is separated from the engagement surface **50** near the proximal end **52** of arm **53** and slopes toward the engagement surface **50** near the free end **54** with the free end of the gripper element **16** contacting engagement surface **50**, as illustrated in FIG. **16**. This shape of the gripper elements **16** can accommodate valve leaflets or other tissues of varying thicknesses.

In the illustrated embodiment, gripper elements **16** can include a plurality of openings **63** and/or scalloped side edges **61** to increase grip on tissue. The gripper elements **16** optionally include frictional accessories, frictional features or grip-enhancing elements to assist in grasping and/or holding the leaflets. In some embodiments, the frictional accessories include barbs **60** having tapering pointed tips extending toward engagement surfaces **50**. It may be appreciated that any suitable frictional accessories may be used, such as prongs, windings, bands, barbs, grooves, channels, bumps, surface roughening, sintering, high-friction pads, coverings, coatings or a combination of these.

In some embodiments, magnets may be present in the gripper elements **16** and/or distal elements **18**. For example, the mating surfaces can be made from or may include material of opposite magnetic charge to cause attraction by magnetic force. For example, the gripper elements **16** and distal elements **18** may each include magnetic material of opposite charge so that tissue is held under constant compression between the gripper elements **16** and distal elements **18** to facilitate faster healing and ingrowth of tissue. The magnetic force may additionally or alternatively be used to draw the gripper elements **16** toward the distal elements **18**. This may assist in deployment of the gripper elements **16**. In another example, the distal elements **18** can each include magnetic material of opposite charge so that tissue positioned between the distal elements **18** is held therebetween by magnetic force.

The implantable device **14** can also include an actuation mechanism. In this embodiment, the actuation mechanism comprises two link members or legs **68**, each leg **68** having a first end **70** which is rotatably joined with one of the distal elements **18** at a riveted joint **76** and a second end **72** which can be rotatably joined with a stud **74**. The legs **68** can be formed of a rigid or semi-rigid metal or polymer such as Elgiloy®, cobalt chromium or stainless steel; however, any suitable material may be used. While in the embodiment illustrated both legs **68** are pinned to stud **74** by a single rivet **78**, in other embodiments, each leg **68** may be individually attached to the stud **74** by a separate rivet or pin. The stud **74** may be joinable with an actuator rod (not shown) which extends through the shaft **12** and can be axially extendable and retractable to move the stud **74** and therefore the legs **68** to rotate the distal elements **18** between closed, open and/or inverted positions. Immobilization of the stud **74** can hold the legs **68** in place and therefore hold the distal elements **18** in a desired position. The stud **74** may also be locked in place by a locking feature which will be further described in later sections.

FIGS. **17-27** illustrate embodiments of the implantable device **14** of FIG. **16** in various possible positions during introduction and placement of the device **14** within the body to perform a therapeutic procedure. FIG. **17** illustrates an embodiment of an interventional tool **10** delivered through a catheter **86**. It may be appreciated that the interventional tool **10** may take the form of a catheter, and the catheter **86** may take the form of a guide catheter or sheath. In this example the terms interventional tool **10** and catheter **86** will be used. The interventional tool **10** can include an implantable device **14** coupled to a shaft **12**. In FIG. **17**, the implantable device **14** is shown in the closed position.

FIG. **18** illustrates a similar embodiment of the implantable device of FIG. **17** in a larger view. In the closed position, the opposed pair of distal elements **18** may be positioned so that the engagement surfaces **50** face each other. Each distal element **18** can include an elongate arm **53** having a cupped or concave shape so that together the arms

53 surround the shaft 12 and can contact each other on opposite sides of the shaft. This provides a low profile for the implantable device 14 which can be readily passable through the catheter 86 and through any anatomical structures, such as the mitral valve.

FIG. 18 illustrates an actuation mechanism. In this embodiment, the actuation mechanism includes two legs 68 which may each be movably coupled to a base 69. The base 69 may be joined with an actuator rod 64 which extends through the shaft 12 and which may be used to manipulate the implantable device 14. In some embodiments, the actuator rod 64 can attach directly to the actuation mechanism, such as the base 69. However, the actuator rod 64 may alternatively attach to a stud 74 which in turn is attached to the base 69. In some embodiments, the stud 74 can be threaded so that the actuator rod 64 attaches to the stud 74 by a screw-type action. However, the rod 64 and stud 74 may be joined by any mechanism which is releasable to allow the implantable device 14 to be detached from shaft 12.

FIGS. 19-20 illustrate the implantable device 14 in the open position. In the open position, the distal elements 18 can be rotated so that the engagement surfaces 50 face a first direction. Distal advancement of the stud 74 relative to coupling member 19 by action of the actuator rod 64 can apply force to the distal elements 18 which begin to rotate around joints 76 due to freedom of movement in this direction. Such rotation and movement of the distal elements 18 radially outward can cause rotation of the legs 68 about joints 80 so that the legs 68 are directed slightly outwards. The stud 74 may be advanced to any desired distance correlating to a desired separation of the distal elements 18. In the open position, engagement surfaces 50 are disposed at an acute angle relative to shaft 12, such as at an angle of between 90 and 180 degrees relative to each other. In some embodiments, in the open position the free ends 54 of arms 53 have a span therebetween of about 10-20 mm, such as about 12-18 mm, and preferably about 14-16 mm.

Gripper elements 16 can be biased outwardly toward arms 53. The gripper elements 16 may be moved inwardly toward the shaft 12 and held against the shaft 12 with the aid of one or more gripper lines 90, which can be in the form of sutures, wires, nickel-titanium alloy wire, rods, cables, polymeric lines, or other suitable structures. The gripper lines 90 may be connected with the gripper elements 16 by threading the gripper lines 90 in a variety of ways. When the gripper elements 16 have a loop shape, as shown in FIG. 19, a gripper line 90 may pass through the loop and double back. When the gripper elements 16 have an elongate solid shape, as shown in FIG. 20, a gripper line 90 may pass through one or more of the openings 63 in the element 16.

A line loop 48 may be included on a gripper element 16, as illustrated in FIG. 20, through which a gripper line 90 may pass and double back. Such a line loop 48 may be useful to reduce friction on gripper line 90 or when the gripper elements 16 are solid or devoid of other loops or openings through which the gripper lines 90 may attach and/or pass through. A gripper line 90 may attach to the gripper elements 16 by detachable means which would allow a single line 90 to be attached to a gripper element 16 without doubling back and/or would allow the single line 90 to be detached directly from the gripper element 16 when desired. Examples of such detachable means include hooks, snares, clips or breakable couplings. By applying sufficient tension to the gripper line 90, the detachable means may be detached from the gripper element 16 such as by breakage of the coupling. Other mechanisms for detachment may also be used. A lock line 92 may be attached and detached from a locking mechanism by similar detachable means.

The interventional tool 10 may be repeatedly manipulated to reposition the implantable device 14 so that the leaflets are properly contacted or grasped at a desired location. Repositioning can be achieved with the implantable device in the open position. In some instances, regurgitation may also be checked while the device 14 is in the open position. If regurgitation is not satisfactorily reduced, the device may be repositioned and regurgitation checked again until desired results are achieved.

It may also be desired to invert the implantable device 14 to aid in repositioning or removal of the implantable device 14. FIGS. 21-22 illustrate the implantable device 14 in the inverted position. By advancement of stud 74 relative to coupling member 19, the distal elements 18 can be further rotated so that the engagement surfaces 50 face outwardly and free ends 54 point distally, with each arm 53 forming an obtuse angle relative to shaft 12. The angle between arms 53 is preferably in the range of about 270 to 360 degrees. Further advancement of the stud 74 can further rotate the distal elements 18 around joints 76. This rotation and movement of the distal elements 18 radially outward can cause rotation of the legs 68 about joints 80 so that the legs 68 are returned toward their initial position (e.g., generally parallel to each other). The stud 74 may be advanced to any desired distance correlating to a desired inversion of the distal elements 18. Preferably, in the fully inverted position, the span between free ends 54 is no more than about 20 mm, usually less than about 16 mm, and preferably about 12-14 mm.

In this illustration, the gripper elements 16 remain positioned against the shaft 12 by exerting tension on the gripper lines 90. Thus, a relatively large space may be created between the gripper elements 16 and the distal elements 18 for repositioning. In addition, the inverted position allows withdrawal of the implantable device 14 through the valve while minimizing trauma to the leaflets. Engagement surfaces 50 can provide an atraumatic surface for deflecting tissue as the implantable device is retracted proximally. It should be further noted that barbs 60 are angled slightly in the distal direction (away from the free ends of the gripper elements 16), reducing the risk that the barbs will catch on or lacerate tissue as the implantable device is withdrawn.

Once the implantable device 14 has been positioned in a desired location against the valve leaflets, the leaflets may then be captured between the gripper elements 16 and the distal elements 18. FIGS. 23-24 illustrate the implantable device 14 in such a position. Here, the gripper elements 16 are lowered toward the engagement surfaces 50 so that the leaflets can be held therebetween. In FIG. 24, the gripper elements 16 are shown to include barbs 60, which may be used to provide atraumatic gripping of the leaflets. Alternatively, larger, more sharply pointed barbs or other penetration structures may be used to pierce the leaflets to more actively assist in holding them in place. This position is similar to the open position of FIGS. 19-20; however, the gripper elements 16 are now lowered toward arms 53 by releasing tension on gripper lines 90 to compress the leaflet tissue therebetween. At any time, the gripper elements 16 may be raised and the distal elements 18 adjusted or inverted to reposition the implantable device 14 (e.g., if regurgitation is not sufficiently reduced).

After the leaflets have been captured between the gripper elements 16 and distal elements 18 in a desired arrangement, the distal elements 18 may be locked to hold the leaflets in

this position or the implantable device **14** may be returned to or toward a closed position. Such locking will be described in a later section. FIG. **25** illustrates the implantable device **14** in the closed position wherein the leaflets (not shown) can be captured and coapted. This can be achieved by retraction of the stud **74** proximally relative to coupling member **19** so that the legs **68** of the actuation mechanism **58** can apply an upwards force to the distal elements **18**, which in turn rotate the distal elements **18** so that the engagement surfaces **50** again face one another. The released gripper elements **16**, which are biased outwardly toward distal elements **18**, are concurrently urged inwardly by the distal elements **18**. The implantable device **14** may then be locked to hold the leaflets in this closed position.

As shown in FIG. **26**, the implantable device **14** may then be released from the shaft **12**. As mentioned, the implantable device **14** is releasably coupleable to the shaft **12** by coupling member **19**. FIG. **26** illustrates the coupling structure, a portion of the shaft **12** to which the coupling member **19** of the implantable device **14** attaches. As shown, the gripper lines **90** may remain attached to the gripper elements **16** following detachment from shaft **12** to function as a tether to keep the implantable device **14** connected with the catheter **86**. Optionally, a separate tether coupled between shaft **12** and implantable device **14** may be used expressly for this purpose while the gripper lines **90** are removed. The repair of the leaflets or tissue may be observed by non-invasive visualization techniques, such as echocardiography. If the repair is not desired, the implantable device **14** may be retrieved with the use of the tether and/or gripper lines **90** so as to reconnect coupling member **19** with shaft **12**.

The one or more gripper lines **90** may be elongated flexible threads, wire, cable, sutures or lines extending through shaft **12**, looping through gripper elements **16**, and extending back through shaft **12** to its proximal end. When detachment is desired, one end of each line may be released at the proximal end of the shaft **12** and the other end pulled to draw the free end of the line distally through shaft **12** and through gripper element **16** thereby releasing the implantable device.

FIG. **27** illustrates a released implantable device **14** in a closed position. As shown, the coupling member **19** remains separated from the shaft **12** of the interventional tool **10** and the gripper elements **16** are deployed so that tissue (not shown) may reside between the gripper elements **16** and distal elements **18**.

While the above described embodiments of the invention utilize a push-to-open, pull-to-close mechanism for opening and closing distal elements **18**, other embodiments can include a pull-to-open, push-to-close mechanism. For example, distal elements **18** may be coupled at their proximal ends to stud **74** rather than to coupling member **19**, and legs **68** may be coupled at their proximal ends to coupling member **19** rather than to stud **74**. In this example, when stud **74** is pushed distally relative to coupling member **19**, distal elements **18** would close, while pulling on stud **74** proximally toward coupling member **19** would open distal elements **18**.

B. Implantable Device Locking Mechanisms

The implantable device **14** may include a locking mechanism for locking the device **14** in a particular position, such as an open, closed or inverted position or any position therebetween. FIGS. **28-31** illustrate an embodiment of a locking mechanism **106**. Referring to FIG. **28**, in this embodiment, the locking mechanism **106** may be disposed between the coupling member **19** and the base **69** of the actuation mechanism **58**. The base **69** can be fixedly attached to the stud **74** which extends through the locking mechanism **106**. The stud **74** may be releasably attached to the actuator rod **64** which passes through the coupling member **19** and the shaft **12** of the interventional tool **10**. The base **69** can also connected to the legs **68** of the actuation mechanism **58** which are in turn connected to the distal elements **18**.

FIG. **28** also illustrates the gripper elements **16**, which in this embodiment straddle the locking mechanism and join beneath the locking mechanism **106** as an integral gripper. The gripper elements **16** are shown supported by gripper lines **90**. The gripper elements **16** may be raised and lowered by manipulation of the gripper lines **90**. In addition, lock lines **92** are shown connected with a release harness **108** of the locking mechanism **106**. The lock lines **92** may be used to lock and unlock the locking mechanism **106** as will be described below. The gripper lines **90** and lock lines **92** may be formed of any suitable material, such as wire, nickel-titanium alloy wire, cable, suture, or thread, to name a few.

FIG. **29** provides a front view of the locking mechanism **106** of FIG. **28**. In this embodiment, the gripper elements **16** are supported by a single gripper line **90** which is passed through both of the gripper elements **16**. In this arrangement both of the gripper elements **16** are raised and lowered simultaneously by action of a single gripper line **90**. Whether the gripper elements **16** are manipulated individually by separate gripper lines **90** or jointly by a single gripper line **90**, the gripper lines **90** may extend directly through openings in the gripper elements and/or through a layer or portion of a covering **100** on the gripper elements, and/or through a suture loop above or below a covering **100**.

FIGS. **30-31** illustrate an embodiment of a locking mechanism **106** showing the locking mechanism **106** in the unlocked and locked positions, respectively. Referring to FIG. **30**, the locking mechanism **106** can include one or more wedging elements, such as rolling elements. In this embodiment, the rolling elements include a pair of barbells **110** disposed on opposite sides of the stud **74**, each barbell having a pair of generally cylindrical caps and a shaft therebetween. The barbells **110** and the stud **74** can be formed of cobalt chromium or stainless steel, however any suitable material may be used.

The barbells **110** may be manipulated by hooked ends **112** of the release harness **108**. When an upwards force is applied to the harness **108** by the lock line **92** (illustrated in FIG. **28**), the hooked ends **112** can raise the barbells **110** against a spring **114**, as shown in FIG. **30**. This draws the barbells **110** up along a sidewall or sloping surface **116** which unwedges the barbells **110** from against the stud **74**. In this position, the stud **74** is free to move. Thus, when the lock line **92** raises or lifts the harness **108**, the locking mechanism **106** is placed in an unlocked position wherein the stud **74** is free to move the actuation mechanism **58** and therefore the distal elements **18** to any desired position.

Release of the harness **108** by the lock line **92** transitions the locking mechanism **106** to a locked position, illustrated in FIG. **31**. By releasing the upwards force on the barbells **110** by the hooked ends **112**, the spring **114** forces the barbells **110** downwards and wedges the barbells **110** between the sloping surface **116** and the stud **74**. This restricts motion of the stud **74**, which in turn locks the actuation mechanism **58** and therefore distal elements **18** in place. The stud **74** may include one or more grooves **82** or indentations which receive the barbells **110**. This may provide more rapid and positive locking by causing the barbells **110** to settle in a definite position, increase the stability of the locking feature by further preventing movement of the

barbells **110**, as well as providing a tangible indication to the user that the barbell has reached a locking position.

The grooves **82** may be used to indicate the relative position of the distal elements **18**, such as the distance between the distal elements **18**. For example, each groove **82** may be positioned to correspond with a 0.5 or 1.0 mm (or other size) decrease in distance between the distal elements **18**. As the stud **74** is moved, the barbells **110** can contact the grooves **82**; by counting the number of grooves **82** that are felt as the stud **74** is moved, the user can determine the distance between the distal elements **18** and can provide the desired degree of coaptation based upon leaflet thickness, geometry, spacing, blood flow dynamics and/or other factors. Thus, the grooves **82** may provide tactile feedback to the user.

The illustrated locking mechanism **106** allows the implantable device **14** to remain in an unlocked position when attached to the interventional tool **10** during grasping and repositioning and then maintain a locked position when left behind as an implant. The locking mechanism **106** may be repeatedly locked and unlocked throughout the placement of the implantable device **14**, if desired. Once the final placement is determined, the lock line **92** and gripper line **90** are removed and the implantable device can be left behind.

IV. Delivery Device

A. Overview of Delivery Device

FIG. **32** illustrates an embodiment of a delivery device **300** which may be used to introduce and position an implantable device at a target location as described above. As illustrated, the delivery device **300** can include a proximal end **322** and a distal end **324**, and a shell **306** disposed between the proximal end **322** and distal end **324**. As described in further detail below, the shell **306** can be configured to hold and/or position various components passing from the proximal end **322** toward the distal end **324**, such as lock lines, gripper lines, actuator rod components, and the like.

As shown, a fluid management system **308** can be coupled to the shell **306** and can extend distally from the shell **306**. A delivery catheter **302** can be coupled to the fluid management system **308** and can extend distally from the fluid management system **308**. As described in further detail below, the fluid management system **308** can be configured to gather and/or direct various components (e.g., lock lines, gripper lines, actuator rod) passing from the proximal side **322** to the distal side **324** so as to position the various components within the delivery catheter **302**. The fluid management system **308** can be configured to receive a fluid to be flushed into the delivery catheter **302** and/or to seal off other components of the delivery device **300** (e.g., shell **306** and/or other components located proximal to the fluid management system **308**) in order to provide dry operation of the other components of the delivery device **300**.

The illustrated delivery device **300** can include a translation knob **304** coupled to the shell **302** and extending proximally from the shell **302**. The translation knob **304** may be configured as a handle and/or gripping surface. For example, the translation knob **304** can allow a user to position the delivery device **300** (e.g., by rotating and/or translating) by providing a surface for gripping and/or handling the delivery device **300**. As shown, the translation knob **304** may include one or more fins and/or grooves arranged to aid a user in manipulating the delivery device **300**.

The delivery device **300** may include a collar **310**, at least a portion of which may be positioned proximal to the translation knob **304**. As described in further detail below, the collar **310** may be configured as a control for one or more gripper lines (not shown) and/or lock lines (not shown) in order to, for example, position the gripper elements and/or adjust the locking of an attached implantable device (e.g., the implantable device **14** shown in FIGS. **16-31**). For example, the collar **310** can be configured so as to be translatable along a shaft **312**, and the collar **310** can be configured to apply or release tension in one or more gripper lines and/or to apply or release tension in one or more lock lines by sliding of the collar **310** proximally or distally along the shaft **312**.

The delivery device **300** may include a deployment handle **314** disposed proximal to the shaft **312**. As described in further detail below, the deployment handle **314** may be configured to actuate movement of an actuator rod (not shown) in order to, for example, position the distal elements of an attached implantable device (e.g., the implantable device **14** shown in FIGS. **16-31**). In addition, as described in further detail below, the deployment handle **314** may be configured to provide staged deployment of an attached implantable device. For example, the deployment handle can be configured to ensure proper deployment of an implantable device by forcing and/or reminding an operator to follow the proper procedure for deploying the implantable device. Further, the deployment handle **314** may be configured to provide control over the locking and/or unlocking of an attached implantable device (e.g., by working in conjunction with the collar **310**).

FIG. **33** illustrates an embodiment of an implantable device **14** coupled to the distal end **324** of a delivery catheter **302**. The delivery catheter **302** is shown having a nose **318** near its distal end **324**. In this embodiment, the nose **318** has a flanged shape. Such a flanged shape prevents the nose **318** from being retracted into a guiding catheter or introducer. In other embodiments, the nose **318** may have any shape including bullet, rounded, blunt, or pointed, to name a few. A compression coil **326** can extend from the nose **318**, through which the coupling structure **320** and/or actuator rod **64** can pass. The actuator rod **64** may be coupleable, as shown, with the stud **74** of the implantable device **14**. Such coupling is illustrated in FIG. **34**.

FIG. **34** illustrates a portion of the delivery catheter **302** and an implantable device **14** which is coupleable with a delivery catheter **302**. The actuator rod **64** can pass through the delivery catheter **302**. In this embodiment, the actuator rod **64** comprises a proximal extremity **303** and a distal extremity **328**. The distal extremity **328** may be surrounded by a coil **330**. The proximal extremity **303** may be formed of stainless steel, nickel-titanium alloy, and/or ELGILOY®, to name a few, and may have a diameter in the range of 0.010 in. to 0.040 in., preferably 0.020 in. to 0.030 in., more preferably 0.025 in., and a length in the range of 48 to 72 in. The distal extremity **328** may be tapered, is typically formed of stainless steel, nickel-titanium alloy, and/or ELGILOY®, to name a few, and may have a diameter in the range of 0.011 to 0.025 in and a length in the range of 4 to 12 in. Such narrowing increases flexibility of the distal end **324** of the actuator rod **64**.

The actuator rod **64** may include a joiner **332** attached to the distal extremity **328**. The joiner **332** may be removably attachable with stud **74** of the implantable device **14**. In this embodiment, the joiner **332** has internal threads which can mate with external threads on the stud **74** of the implantable device **14**. As described previously, the stud **74** may be

connected with the distal elements **18** so that advancement and retraction of the stud **74**, by means of the actuator rod **64**, manipulates the distal elements. The coupling member **19** of the implantable device **14** can mate with the coupling structure **320** of the catheter **300**. Thus, the coupling member **19** and coupling structure **320** can function as previously described in relation to FIGS. **10-11**.

Referring back to FIG. **33**, the implantable device **14** may also include a locking mechanism which includes a release harness **108**, as previously described in relation to FIGS. **28-31**. Lock lines **92** may be connected with the release harness **108** to lock and unlock the locking mechanism **106**. The lock lines **92** may extend through the delivery catheter **302** and may connect with the release harness **108** in various arrangements as described in further detail below. Gripper lines **90** may extend through the delivery catheter **302** and connect with the gripper elements **16**. The gripper elements **16** can be raised and lowered by manipulation of the gripper lines **90** as previously described. The gripper lines **90** may connect with the gripper elements **16** in various arrangements as described in further detail below.

B. Lock Line Arrangements

In embodiments including one or more lock lines **92**, the lock lines **92** can pass through at least one lock line lumen **340** in the delivery catheter **302**. The lock lines **92** may engage the release harnesses **108** in various arrangements, examples of which are illustrated in FIGS. **35-37**. In the illustrated embodiments, two lock line lumens **340** are present within the delivery catheter **302** terminating at the nose **318**. The lumens **340** can be disposed on alternate sides of the actuator rod **64** so that each lumen **340** is directed toward a release harness **108**.

FIG. **35** illustrates an embodiment wherein two lock lines **92**, **92'** pass through a single lock line lumen **340** and are threaded through a release harness **108** on one side of the actuator rod **64** (the actuator rod **64** is shown without surrounding housing such as coupling structure, for clarity). The lock lines **92**, **92'** can then be separated so that each lock line passes on an opposite side of the actuator rod **64**. The lock lines **92**, **92'** can then pass through the release harness **108'** on the opposite side of the actuator rod **64** and continue together passing through a another single lock line lumen **340'**. This lock line arrangement is also illustrated in FIG. **33**.

FIG. **36** illustrates an embodiment wherein one lock line **92** can be passed through a single lock line lumen **340**, can be threaded through a release harness **108** on one side of the actuator rod **64**, and can be returned to the lock line lumen **340**. Another lock line **92'** can be passed through another single lock line lumen **340'**, can be threaded through a different release harness **108'** located on the opposite side of the actuator rod **64**, and can be returned to the another single lock line lumen **340'**.

FIG. **37** illustrates an embodiment wherein both lock lines **92**, **92'** can be passed through a single lock line lumen **340**. One lock line **92** can be threaded through a release harness **108** on one side of the actuator rod **64** and can then be passed through another lock line lumen **340'** on the opposite side of the actuator rod **64**. The other lock line **92'** can be threaded through another release harness **108'** on the other side of the actuator rod **64** and can then be passed through the another lock line lumen **340'** with the previous lock line **92**.

Other embodiments may include a variety of lock line arrangements. Various arrangements can be configured to allow the harnesses **108** to be manipulated independently or jointly, to allow various amounts of tension to be applied, and/or to vary the force required for removal of the lock lines when the implantable device is to be left behind. For example, a single lock line passing through one or two lumens may be connected to both release harnesses for simultaneous application of tension.

C. Gripper Line Arrangements

In embodiments including gripper lines **90**, the gripper lines **90** can be passed through at least one gripper line lumen **342** in the delivery catheter **302** and at least one gripper element **16**. The gripper lines **90** may engage the gripper elements **16** in various arrangements, examples of which are illustrated in FIGS. **38-39**. In the illustrated embodiments, two gripper line lumens **342** are present within the delivery catheter **302** terminating at the nose **318**. The lumens **342** can be disposed on alternate sides of the actuator rod **64** (the actuator rod **64** is shown without surrounding housing such as coupling structure, for clarity) so that each lumen **342** is directed toward a separate gripper element **16**.

FIG. **38** illustrates an embodiment wherein one gripper line **90** passes through a single gripper line lumen **342**. The gripper line **90** can be threaded through an eyelet **360** of a gripper element **16** on one side of the actuator rod **64**, passed over the actuator rod **64**, and be threaded through an eyelet **360'** of another gripper element **16'** on the other side of the actuator rod **64**. The gripper line **90** can then be passed through another single gripper line lumen **342'**. This gripper line arrangement is the same arrangement illustrated in FIG. **33**.

FIG. **39** illustrates an embodiment wherein one gripper line **90** can be passed through a single gripper line lumen **342**, can be threaded through an eyelet **360** of a gripper element **16** on one side of the actuator rod **64**, and can then be returned to the gripper line lumen **342**. Optionally, another gripper line **90'** can be passed through another single gripper line lumen **342'** on the opposite side of the actuator rod **64**, and can be returned to the another single gripper line lumen **342'**.

Other embodiments may include a variety of gripper line arrangements. The various arrangements can allow the gripper elements to be manipulated independently or jointly, allow various amounts of tension to be applied, and/or can vary the force required for removal of the gripper lines when the implantable device is to be left behind. For example, a single gripper line passing through one or two lumens in the delivery catheter **302** may be used for simultaneous actuation of both gripper elements **16**. In addition, snares or hooks may be mounted within delivery catheter **302** so as to be movable distally to engage gripper elements **16** and draw them away from distal elements **18**.

D. Fluid Management System

FIG. **40** illustrates a cutaway view of the fluid management system **308** illustrated in FIG. **32**. As illustrated, the fluid management system **308** can include a grommet **316**. The delivery catheter **302** can be coupled to the grommet **316** and can extend distally from the grommet **316** (e.g., out of the delivery catheter outlet **335**). As shown in the illustrated embodiment, the grommet **316** can be formed with an interior lumen configured in size and shape to engage with the delivery catheter **302** in order to allow the delivery catheter **302** to be coupled to the grommet **316**. For example, the proximal end of the delivery catheter **302** may be inserted into an interior lumen **336** of the grommet **316**.

The grommet **316** may be housed inside a flush body **333**. As shown in the illustrated embodiment, the flush body **333** can be formed with a cylindrical shape. The flush body **333** can include a delivery catheter outlet **335**, a fluid inlet **337**, and an opening **344**. The fluid inlet **337** can be configured to

receive fluids (e.g., saline, heparinized saline, and/or other fluids with or without other drugs) for delivery into the delivery catheter **302**. In the illustrated embodiment, the flush body **333** is formed with a cylindrical shape. In other embodiments, the flush body **333** may be formed in other shapes, such as shapes having triangular, square, rectangular, or other polygonal cross-sections, or ovoid or ellipsoid cross-sections.

In the illustrated embodiment, the delivery catheter outlet **335** and the fluid inlet **337** are positioned with longitudinal axes that are transverse to each other, with the delivery catheter outlet **335** being positioned on a distal face **339** of the flush body **333** and the fluid inlet **337** is positioned on a side portion **341** of the flush body **333**. In other embodiments, the flush body **333** may include a delivery catheter outlet **335** and/or a fluid inlet **337** that are oriented in an alternative arrangement. For example, some embodiments may include a delivery catheter outlet and a fluid inlet that are both oriented on a distal face of a flush body. Other embodiments may include a delivery catheter outlet and a fluid inlet that are both oriented on a side portion of a flush body. Other embodiments may include a delivery catheter outlet oriented on a side portion of a flush body and a fluid inlet oriented on a distal face of the flush body, for example.

The opening **344** can be disposed at a proximal end of the flush body **333**, as shown. In other embodiments, the opening can be disposed at the side portion **341** or the distal face **339** of the flush body **333**.

The fluid inlet **337** may be configured to allow the introduction of a fluid into an interior space **343** within the flush body **333**. As shown, a valve **334** may be positioned within and/or above the fluid inlet **337**. The valve **334** may be configured to check fluid flow across the valve, such as by preventing the introduction and/or release of fluid into or from the interior space **343**. For example, the valve **334** can be a Luer activated valve configured to check fluid flow until mechanically opened with a Luer standard connection and/or device (e.g., a Luer connection associated with tubing and/or other fluid delivery line).

The grommet **316** can be configured to be in fluid communication with the interior space **343**, such that fluid introduced into the interior space **343** can move from the interior space **343** into the interior lumen **336** of the grommet **316**. Fluid within the interior lumen **336** can then be introduced into the delivery catheter **302** for delivery, for example, to a tissue treatment site (e.g., at or near the location of an attached implantable device coupled to the distal end of the delivery catheter **302**). For example, in some embodiments, the grommet **316** can include one or more holes (not shown) allowing fluid to pass from the interior space **343** into the interior lumen **336**. Additionally, or alternatively, the grommet **336** can be formed (or partially formed) of a fluid-permeable substance that allows fluid transfer across the grommet **336**.

As shown in the illustrated embodiment, the fluid management system **308** can include an outlet seal **338** disposed at or near the delivery catheter outlet **335**. The outlet seal **338** can be configured to prevent the passage of fluid from the interior space **343** through the delivery catheter outlet **335** without being passed through the delivery catheter **302**. As shown, the outlet seal **338** can be positioned between the interior portion of the distal face **339** and the grommet **316**. In the illustrated embodiment, the outlet seal **338** is formed as an O-ring positioned around the delivery catheter **302**. Other embodiments can include other sealing means, such as one or more gaskets, plugs, stoppers, and/or caulked or other filled-in areas.

FIG. **40** illustrates that the fluid management system **308** can include additional structures for preventing unwanted passage of fluid through the delivery catheter outlet **335**. In the illustrated embodiment, the outlet seal **338** is positioned within an outlet seal cavity defined by a rim **349**. The rim **349** can, for example, position the outlet seal **338** in the proper orientation relative to the grommet **316**, the delivery catheter **302**, and/or the delivery catheter outlet **335** to ensure the integrity of the resulting fluid seal. The rim **349** can extend from the interior side of the distal face **339** to the grommet **316**, thereby forming an additional barrier that can separate the outlet seal **338** from fluid contained in the interior space **343**.

As illustrated, the grommet **316** can include a lip **345** extending to the interior wall of the flush body **333**. The lip **345** can be positioned so as to separate a portion of the interior space **343** that is in fluid communication with the fluid inlet **337** from a portion closer to the distal face **339** of the flush body **333**. Such a configuration can, for example, provide a barrier (e.g., in addition to a barrier provided by the outlet seal **338** and/or rim **349**) between fluid within the interior space **343** and the delivery catheter outlet **335**.

The illustrated embodiment can include an insert **347** disposed at the opening **344** of the flush body **333**. The insert **347** may extend through the opening **344** to the grommet **316** and/or may be configured to engage with the grommet **316** (e.g., by coupling to the grommet **316** via matching push fit structures, threads, tabs, and/or other coupling means). As shown, the insert **347** can include an opening seal **346** configured to prevent the passage of fluid from the interior space **343** out through the opening **344**. The opening seal **346** can be positioned within a slot formed in the exterior of the insert **347**. The opening seal **346** can be formed as an O-ring, as in the illustrated embodiment. Other embodiments can include other sealing means, such as one or more gaskets, plugs, stoppers, and/or caulked or otherwise filled-in areas.

As illustrated, the fluid management system **308** can include a core **348** disposed at least partially within the interior lumen **336** of the grommet **316**. The core **348** can extend through the insert **347** and into the interior lumen **336** of the grommet **316**. The core **348** can be configured to receive various components of the delivery device **300** (e.g., one or more gripper lines, lock lines, and/or actuator rods) passing through the fluid management system **308** to gather and/or direct the components toward the delivery catheter **302**. For example, the core **348** can include one or more interior lumens configured to receive one or more components of the delivery device **300** and direct it/them into the interior lumen **336** and toward the delivery catheter **302**.

The illustrated embodiment can include a diaphragm **350** positioned proximal to the core **348** and/or insert **347**. The diaphragm **350** can be configured to allow passage of various components (e.g., one or more gripper lines, lock lines, and/or actuator rods) into the interior of the flush body **333** (e.g., into the core **348** and/or into coinciding lumens within the core **348**). The diaphragm **350** can be configured to form a fluid seal separating fluid on a distal side of the diaphragm **350** (e.g., fluid within the grommet **316** and/or core **348**) from areas on a proximal side of the diaphragm **350**, such as manifold **352** described below.

The manifold **352** can be positioned proximal to the diaphragm **350** and the proximal opening **344** (e.g., such that it is exterior to the flush body **333**). The manifold **352** can be configured to receive various components (e.g., one or more gripper lines, lock lines, and/or actuator rods) at a manifold opening **354** and direct the components toward the

diaphragm **350** and/or interior space **343**. As shown in the illustrated embodiment, the manifold can include an inner cavity **356** extending from the manifold opening **354** a distance toward the diaphragm **350**. One or more conduits **358** can extend between the inner cavity **356** and the diaphragm **350**. Each of the one or more conduits **358** can be configured to receive a gripper line, lock line, actuator rod, etc. and direct it/them toward a receiving portion of the diaphragm **350**.

The core **348**, insert **347**, and/or manifold **352** can be configured as a conducting assembly. For example, the core **348**, insert **347**, and/or manifold **352** (independently, as a pair, or in conjunction) can be configured to gather one or more components of the delivery device **300** (e.g., gripper line, lock line, actuator rod) and direct it/them into the interior lumen **336** of the grommet **316**. In some embodiments, the conducting assembly can include one or more lumens configured to receive the one or more components of the delivery device **300**. In some embodiments, the conducting assembly can be disposed at and/or through the opening **344** of the flush body **333**.

The illustrated embodiment includes various adjoining and/or coupled components which are formed separately. In other embodiments, coupled and/or adjoining components may be integrally formed as one component. For example, in some embodiments, a grommet **316**, an insert **347**, a core **348**, and/or a diaphragm **350** may be formed as one integral piece. In some embodiments, one or more of the components of a conducting assembly can be formed as one integral piece.

Embodiments of a fluid management system according to the present disclosure can provide a number of benefits. For example, the configuration of the flush body **333** relative to the diaphragm **350**, insert **347**, core **348**, grommet **316**, and/or delivery catheter **302** can eliminate the need for a large fluid reservoir (e.g., a fluid reservoir extending into the shell **306** or other components of the delivery device **300** located proximal to the fluid management system **308**). Relative to configurations requiring a large fluid reservoir, embodiments of the present disclosure can minimize the area to be fluidly sealed from the remainder of the device and/or minimize the amount of fluid required to be held within the device at a given time. Accordingly, with less area to be sealed and/or less fluid present, the risk of leaks, spills, and/or associated equipment failure resulting from unwanted fluid transport can be beneficially reduced.

In addition, at least some of the fluid management system embodiments of the present disclosure can eliminate the need for a visual fluid reservoir (e.g., one including and/or requiring viewing windows to monitor fluid levels) located on and/or within the delivery device. For example, a fluid management system according to the present disclosure can allow a fluid reservoir and/or fluid monitoring system to be decoupled from the delivery device (e.g., detached from the delivery device and fluidly connected to the fluid management system via one or more tubes, lines, etc.).

FIG. **41** illustrates another embodiment of a flush body **433** including a fluid inlet **437**, a side portion **441**, and a position indicator **460**. The position indicator **460** can be configured to extend through a housing positioned over a portion of the delivery device **300** (see, e.g., FIG. **61**), allowing a user to gauge the position of the delivery device **300** relative to the housing. As shown in FIG. **41**, the position indicator **460** can extend from the side portion **441**. The position indicator **460** may be positioned on the side portion **441** at a location opposite the fluid inlet **437**, as illustrated. In other embodiments, the position indicator **460** and the fluid inlet **437** may be offset by 30, 60, 90, 120, or 150 degrees, for example. The position indicator **460** and the fluid inlet **437** may be circumferentially aligned, as illustrated. In other embodiments, the position indicator **460** and the fluid inlet **437** may be offset, such that one or the other is disposed closer to a proximal end or a distal end.

E. Gripper Line Control

Embodiments of the present disclosure can include one or more control line assemblies for managing one or more control lines (e.g., gripper lines **90** and/or lock lines **92**). As described in more detail below, a line assembly can be configured as a gripper line assembly or a lock line assembly.

FIGS. **42-43** illustrate an embodiment of a line assembly useful for managing one or more gripper lines. FIGS. **42-43** show a cutaway view of a first side of the delivery device **300** shown in FIG. **32**, showing the shell **306**, collar **310**, shaft **312**, translation knob **304**, and a portion of the deployment handle **314**. As illustrated, the delivery device **300** can include a shuttle **364** slidably disposed within the shaft **312**. The shuttle **364** can be coupled to a gripper line hub **366** that extends proximally from the shuttle **364** through the shaft **312** and through a housing lid **368**. FIG. **46** illustrates the shuttle **364**, gripper line hub **366**, and gripper line **90**, with other components of the delivery device removed for clarity. As shown, and as described in more detail below, the shuttle **364** can include one or more tabs **372**.

Referring to FIGS. **42-43**, a gripper line cap **370** may be coupled to the proximal end of the gripper line hub **366**. As shown, the ends of a gripper line **90** (or in alternative embodiments, more than one gripper line) may be passed through the gripper line hub **366** before terminating at the gripper line cap **370**. The gripper line cap **370** can be configured to secure the gripper line **90**. For example, the gripper line cap **370** can be formed as a threaded cap configured to mate with matching threads on the gripper line hub **366**. In such embodiments, the terminating portions of the gripper line **90** can be secured between the gripper line hub **366** and the gripper line cap **370**.

In some embodiments, at least a portion of the gripper line **90** can be housed in a gripper line sheath. For example, one or more gripper line sheaths can be positioned over the gripper line **90** at the portion of the gripper line **90** secured by the threads of the gripper line cap **370**. The one or more sheaths can be attached to the gripper line at desired locations, such as by using an adhesive and/or overmolding the sheaths. The one or more sheaths may be formed of a polymer material providing anti-slippage and/or greater attachment strength when the griper line **90** is coupled to the gripper line cap **370**. In some embodiments, one or more gripper line sheaths may also be attached at other portions of the gripper line **90**, such as at or near areas of the gripper line **90** contacting the shuttle **364** and/or other components of the delivery device **300**.

The gripper line **90** may be manipulated by actuation of the collar **310**. As shown in the illustrated embodiment, the collar **310** can be configured to be translatable along the shaft **312**. Translation of the collar **310** upon the shaft **312** can cause the shuttle **364** to translate within the shaft **312**, thereby applying or releasing tension to the gripper line **90**. For example, the embodiment illustrated in FIGS. **42-43** shows the collar **310** and shuttle **364** in a "down" configuration. In this configuration, the shuttle **364** is positioned distally within the shaft **312**.

From the illustrated configuration, the collar **310** can be actuated so as to translate upon the shaft **312** (e.g., distally and/or proximally). As shown, the collar **310** can include an

outer flange extending radially outward at an angle transverse to the longitudinal axis of the collar and configured to provide a gripping area for actuating the collar **310**. Proximal movement of the collar **310** can cause an inner flange **362** of the collar **310** to engage with one or more tabs **372** formed in and/or extending outward from the shuttle **364**. Engagement of the inner flange **362** against the one or more tabs **372** can thereby cause the shuttle **364** to translate with the collar **310**. For example, as the inner flange **362** engages against the tabs **372**, further proximal movement of the collar **310** along the shaft **312** will coincide with proximal movement of the shuttle **364** within the shaft **312**.

As shown, proximal movement of the collar **310** can move the shuttle **364** until the tabs **372** reach one or more stops **376** disposed within a sidewall and/or formed as part of a sidewall of the shaft **312**. Further proximal movement of the shuttle **364** (e.g., via further proximal movement of the collar **310**) can cause the tabs **372** to flex inwardly, allowing the tabs **372** to move proximally past the stops **376**. Upon moving proximally past the stops **376**, the tabs **372** can flex outwardly back toward a relaxed configuration, allowing the tabs **372** to extend into tab slots **378** disposed in the sidewall of the shaft **312**. Thus, as shown, the tabs **372** can be configured to flex outwardly into the tab slots **378** when positioned adjacent to the tab slots **378**.

As illustrated, the tabs **372** can be formed with an angled and/or tapered surface (e.g., tapering from a larger width to a smaller width along a proximal direction), allowing the shuttle **364** to move proximally past the stops **376** but preventing the shuttle **364** from moving distally backwards after the tabs **372** have extended into the tab slots **378**.

In other embodiments, additional and/or alternative securing means may be included, such as clamps, catches, stops, detents, and the like. In some embodiments, a plurality of lock tabs may be included. In some embodiments, one or more lock tabs may be configured as a hook, plug, insert, press-fit element, or other structure capable of lodging within and/or fastening against a lock slot. In some embodiments, one or more lock slots may be configured as a hole, aperture, receiving cavity, press-fit element, or other structure capable of lodging within and/or fastening against a lock tab. In some embodiments, a lock tab and/or lock slot can include magnetic properties so as to form a magnetic coupling for holding the lock tab against and/or within the lock slot.

In this configuration, the collar **310** and shuttle **364** can be in an "up" configuration. In such a configuration, the shuttle **364** can be positioned proximally within the shaft **312**. Positioning of the shuttle **364** in a proximal position can cause the gripper line **90** to be moved proximally. Such proximal movement of the gripper line may adjust an implantable device associated with and/or attached to the gripper line. For example, proximal movement of the gripper line **90** may raise gripper elements of an implantable device attached to the distal end of the delivery catheter, as described above.

Referring back to FIG. **32**, the shaft **312** and/or collar **310** can include one or more gripper position indicators **382**. The embodiment illustrated in FIG. **32** shows, for example, that the shaft can provide an indication to a user that the gripper line is in a distal and/or down configuration when the position indicator **382** is visible. Additionally, or alternatively, the collar **310** can include one or more position indicators (not shown). For example, the collar **310** can include one or more position indicators that are only visible when the collar **310** has been moved proximally into an open configuration. The collar **310** can thereby indicate to a user that the gripper line is in a proximal and/or up configuration when a position indicator located on the collar **310** is visible and/or when the gripper position indicator(s) **382** of the shaft **312** have been covered by the collar **310**.

As illustrated in FIGS. **42-43**, the collar **310** can include an interior projection **380**. The interior projection **380** can be configured to engage with the tabs **372** and/or press the tabs **372** inwards. As shown, when the collar **310** is moved distally, an angled surface of the interior projection **380** can press against the tabs **372** and force the tabs **372** inwards. For example, when the shuttle **364** and collar **310** are in an up configuration, the collar **310** may be moved distally. Distal movement of the collar **310** can allow the interior projection **380** to press against the tabs **372**, moving the tabs **372** out of their respective tab slots **378**. As the tabs **372** are removed from the tab slots **378**, the shuttle **364** can be further moved distally (e.g., to the down configuration).

The delivery device **300** can include a shuttle return spring **374** configured to apply a force for positioning and/or maintaining the shuttle **364** toward a default position within the shaft **312** (e.g., toward the down configuration as in the illustrated embodiment). For example, upon releasing the tabs **372** from the tab slots **378** so as to allow the shuttle **364** to be moved distally from the up configuration toward the down configuration, the shuttle return spring **374** can expand to push the shuttle **364** distally toward the down configuration. As shown, the shuttle return spring **374** can be positioned around the gripper line hub **366**. In other embodiments, one or more coil springs, leaf springs, and/or other resilient members may be included at other locations in order to push and/or pull a shuttle into a default position.

F. Lock Line Control

FIGS. **44-45** illustrate an embodiment of a line assembly useful for managing one or more lock lines. FIGS. **44-45** show a cutaway view of a second side of the delivery device **300** shown in FIG. **32**. As illustrated, delivery device **300** can include a carriage **384** slidably disposed within the shaft **312**. The carriage **384** may be positioned proximal to the shuttle **364**. As shown, the carriage **384** may be configured in size and shape to engage with the shuttle **364**, such that when the shuttle **364** is moved proximally, the shuttle **364** abuts against and translates the carriage **384** proximally and/or such that when the carriage **384** is moved distally, the carriage **384** abuts against and translates the shuttle **364** distally.

The illustrated carriage **384** can be coupled to a lock line hub **386** that extends proximally from the carriage **384** through the housing lid **368**. A lock line **92** may be coupled to the proximal end of the lock line hub **386**. As shown, a lock line **92** (or in alternative embodiments, more than one lock line) may be passed through the lock line hub **386** before terminating at the lock line cap **390**. The lock line cap **390** can be configured to secure the lock line **92**. For example, the lock line cap **390** can be formed as a threaded cap configured to mate with matching threads on the lock line hub **386**. In such embodiments, the terminating portions of the lock line **92** can be secured between the lock line hub **386** and the lock line cap **390**.

In some embodiments, at least a portion of the lock line **92** can be housed in a lock line sheath. For example, one or more lock line sheaths can be positioned over the lock line **92** at the portion of the lock line **92** secured by the threads of the lock line cap **390**. The one or more sheaths can be attached to the lock line at desired locations, such as by using an adhesive and/or overmolding the sheaths to the lock line **92**. The one or more sheaths may be formed of a polymer material providing anti-slippage and/or greater

attachment strength when the lock line **92** is coupled to the lock line cap **390**. In some embodiments, one or more lock line sheaths may also be attached at other portions of the lock line **92**, such as at or near areas of the lock line **92** contacting the carriage **384** and/or other components of the delivery device **300**.

The lock line **92** may be manipulated by actuation of the collar **310**. As described above, translation of the collar **310** upon the shaft **312** can cause the shuttle **364** to translate within the shaft **312**. Proximal movement of the shuttle **364** can cause proximal movement of the carriage **384** (e.g., via mechanical communication between the shuttle **364** and the carriage **384**), thereby applying or releasing tension to the lock line **92**. Thus, in such embodiments, actuation of the gripper and/or gripper line **90** into the up configuration can also cause locking of an implantable device (e.g., via the locking mechanism **106** shown in FIGS. **28-31**) attached to the delivery device **300**.

The carriage **384** may include a lock tab **392**. The lock tab **392** may be configured to be passable through a lock slot **394** disposed in the housing lid **368**, as illustrated. The lock tab **392** and/or lock slot **394** can be configured such that the lock tab **392** can be lodged and/or otherwise held in position by the lock slot **394** after passing through the lock slot **394**. For example, after the lock tab **392** has passed through the lock slot **394**, the lock tab **392** can be positioned such that a flared portion **396** of the lock tab **392** resists and/or prevents the lock tab **392** from passing back through the lock slot **394**. In the illustrated embodiment, the lock slot **394** includes a narrow width section (e.g., narrower than the section in which the lock tab **392** passes freely) that can provide this function. For example, the flared portion **396** of the lock tab **392** can prevent the lock tab **392** from passing through the lock slot **394** when the lock tab **392** is positioned in the narrow width section.

In other embodiments, additional and/or alternative securing means may be included, such as clamps, catches, stops, detents, and the like. In some embodiments, a plurality of lock tabs may be included. In some embodiments, one or more lock tabs may be configured as a hook, plug, insert, press-fit element, or other structure capable of lodging within and/or fastening against a lock slot. In some embodiments, one or more lock slots may be configured as a hole, aperture, receiving cavity, press-fit element, or other structure capable of lodging within and/or fastening against a lock tab. In some embodiments, a lock tab and/or lock slot can include magnetic properties so as to form a magnetic coupling for holding the lock tab against and/or within the lock slot.

As shown, the lock tab **392** may be configured in size and shape so as to extend through the housing lid **368** when the carriage **384** is positioned in a proximal-most position, and to not extend through the housing lid **368** when the carriage **384** is positioned in a distal-most position.

In the illustrated embodiment, the lock line assembly may be moved from a locked position into an unlocked position by manipulating the portion of the lock tab **392** extending proximally through the lock slot **394**. For example, adjusting the lock tab **392** to allow the lock tab **392** to pass through the lock slot **394** (e.g., by positioning the flared portion **396** so as to fit through a wider portion of the lock slot **394**) can allow the carriage **384** to be moved distally, thereby moving the lock line **92** distally (e.g., to unlock an attached implantable device). In some embodiments, the lock line assembly may be moved toward an unlocked configuration by dislodging the lock tab **392** from the lock slot **394**.

The delivery device **300** can also include a carriage return spring **398** configured to apply a force for positioning the carriage **384** toward a default (e.g., toward the unlocked configuration). For example, upon adjusting the lock tab **392** so as to allow the carriage to be moved distally from the locked configuration toward the unlocked configuration, the carriage return spring **398** can expand to push the carriage **384** distally toward the unlocked configuration. As shown, the carriage return spring **398** can be positioned around the lock line hub **386**. In other embodiments, one or more coil springs, leaf springs, and/or other resilient members may be included to push and/or pull a carriage into position.

F. Actuator Rod Control

FIG. **47** illustrates a cutaway view of a first side of the delivery device **300** shown in FIG. **32**, showing various components of an actuator rod control system disposed within the deployment handle **314**. As illustrated, the delivery device **300** can include an actuator rod **64** that is coupled to a crimp **301** and that extends from the crimp **301** distally to the delivery catheter **302** (not shown). As shown in the illustrated embodiment, the crimp **301** can be secured within an actuator handle **351**. The actuator handle **351** may extend through and beyond the housing lid **368**. As shown, the actuator handle **351** may be coupled to a slider **307**, the slider **307** having threads configured to match with internal threads of an actuator knob **305**. In this configuration, rotation of the actuator knob **305** can cause the slider **307** to translate along the actuator knob **305** by action of the threading.

Rotation of the actuator knob **305** can extend or retract (depending on the direction of rotation) the actuator rod **64** in order to manipulate the distal elements **18** of the implantable device **14**. Rotation of the slider **307** itself is prevented by a first end piece **309** that may be positioned adjacent to the slider **307**. Because the crimp **301** can be coupled to the slider **307**, the crimp **301** can translate along with the slider **307**.

The actuator rod **64** may be rotated by rotation of the actuator handle **351**. As illustrated, the actuator handle **351** may be coupled to the slider **305** by threading into the slider **305**. In this configuration, rotation of the actuator handle **351** allows the actuator handle **351** to translate proximally away from the slider **305**, thereby translating actuator rod **64** proximally. As described above, rotation of the actuator rod **64** can engage or disengage a threaded joiner **332** of the delivery catheter **302** from the threaded stud **74** of the implantable device **14** (e.g., to attach or detach the implantable device **14** from the delivery catheter **302**). In addition, when the actuator rod **64** is in a disengaged state, the actuator rod **64** may optionally be retracted and optionally removed from the delivery device **300** by pulling the actuator handle **351** and withdrawing the actuator rod **64** from the delivery device **300** (e.g., after unthreading the actuator handle **351** from the slider **307**).

Some embodiments may include one or more removal tools configured to provide removal and/or adjustment of the actuator rod **64** and/or crimp **301**. As illustrated in FIG. **48**, for example, the crimp **301** may be configured to receive a first removal tool **311**. The first removal tool **311** can optionally be coupled to a second removal tool **313**. The first removal tool **311** and/or second removal tool **313** can be used to adjust and/or remove the crimp **301** from within the actuator handle **351**.

FIG. **49** illustrates the slider **307**, first end piece **309**, actuator handle **351**, actuator rod **64**, and a second end piece **315**, with the actuator knob **305**, shell **306**, and other components removed for clarity. As illustrated, the first end

piece **309** and/or second end piece **315** can be configured to prevent rotation of the slider **307**, allowing the slider to translate distally or proximally upon engagement of the threaded portion of the slider **307** with the inner threads of the actuator knob.

G. Staged Deployment

FIGS. **50-54** illustrate one embodiment of a deployment handle **314** and its components. As shown in FIG. **50**, the deployment handle **314** can include an outer handle cap **317** and an inner handle cap **319**. Rotation of the outer handle cap **317** can cause rotation of the underlying actuator knob **305**, which, as described above, can cause the actuator rod **64** to translate distally and proximally in response (e.g., in order to open and close the distal elements **18** or the implantable device **14**).

The illustrated embodiment of the deployment handle **314** can be configured to provide a staged deployment sequence. The staged deployment sequence can, for example, prevent accidental and/or incorrect deployment steps that could potentially disrupt or prolong a medical procedure and/or which could cause harm to a patient. For example, the deployment handle **314** can be configured so as to force and/or remind a user to perform certain deployment steps prior to other deployment steps. In some embodiments, for example, some steps will not be able to be performed without first removing and/or actuating one or more components of the deployment handle **314**, with the removing and/or actuating ensuring that required and/or preferred prior steps are taken first.

For example, during a tissue repair procedure (e.g., mitral valve fixation), an operator may manipulate the distal elements **18** and/or the gripper **16** (shown, for example, in FIGS. **4-7** and **12-28**) to grasp the targeted tissue, as described above. After obtaining a desired grasp of the target tissue, the user can then close the implantable device **14** (shown, for example, in FIGS. **4-7** and **12-28**) by rotating the outer handle cap **317** so as to actuate the actuator knob **305** and cause the actuator rod (e.g., actuator rod **64**) to translate, as described above. Upon determining a suitable grasp, the operator can begin a staged deployment process by actuating the inner handle cap **319**. As illustrated in FIG. **50**, the inner handle cap **319** can be accessed at the proximal end of the deployment handle **314**. The inner handle cap **319** can be configured to rotate within the outer handle cap **317**.

In the illustrated embodiment, actuation of the inner handle cap **319** causes the implantable device **14** to enter a locked configuration (e.g., as shown in FIG. **4**). As shown in the cutaway view of FIG. **51**, actuation of the inner handle cap **319**, such as by rotating the inner handle cap **319** counterclockwise (as viewed from a perspective proximal to the deployment handle **314**) causes an inner handle cap tab **321** to pass over the lock slot **394**. This motion can ensure that the implantable device **14** is placed in a locked configuration. For example, if the carriage **384** is in an unlocked configuration with the lock tab **392** extending through the lock slot **394**, actuation of the inner handle cap **319** can disengage the lock tab **392** from the lock slot **394**, allowing the carriage **384** to translate distally to place the implantable device **14** in the locked configuration.

After the inner handle cap **319** has been actuated, the outer handle cap **317** and inner handle cap **319** can be removed from the deployment handle **314**. In some embodiments, grooves, channels, stops, detents, and/or other structures can be included in the inner handle cap **319**, the outer handle cap **317**, and/or the housing lid **368** to prevent removal of the outer handle cap **317** and/or inner handle cap **319** until after the inner handle cap **319** has been actuated. For example, the inner handle cap **319** may include grooves that prevent the inner handle cap **319** from being detached from the housing lid **368** until the inner handle cap **319** has been rotated to an actuated position.

FIG. **52** illustrates the deployment handle **314** after the outer handle cap **317** and inner handle cap **319** have been removed. From this configuration, an operator can test rotation of the exposed actuator knob **305** in order to perform a final arm angle check (FAA check). For example, an operator can attempt to rotate the actuator knob **305** to open the distal elements **18** of the implantable device **14** as part of the FAA check. If the implantable device **14** has been properly placed in a locked configuration by the prior deployment steps, then the operator will be unable to or be limited in rotating the actuator knob **305**. Additionally, or alternatively, an operator may use the actuator knob **305** to perform an FAA check at other times during deployment, such as after actuating the inner handle cap **319** but prior to removing the outer handle cap **317** and inner handle cap **319**, and/or after removing the lock line **92**, for example.

As shown, in FIG. **52**, the deployment handle **314** can include a lockout **323** configured to prevent an operator from accessing the lock line cap **390** (hidden by the lockout **323** in FIG. **52**) prior to performing steps associated with the gripper line cap **370**. In this embodiment, the lockout **323** can prevent an operator from inadvertently and/or mistakenly accessing the lock line cap **390** and/or lock line **92** prior to performing preferred and/or required steps involving the gripper line **90** and/or gripper line cap **370**. As shown, the lockout **323** can include a lockout lip **325** positioned underneath (i.e., distal to) the gripper line cap **370**. This configuration can prevent the lockout **323** from being removed prior to removal of the gripper line cap **370**. For example, the lockout lip **325** can be configured in size and shape so as to prevent movement of the lockout prior to removal of the first control line cap.

For example, from the configuration shown in FIG. **52**, an operator can disengage the gripper line cap **370** to reveal the gripper line **90**. The gripper line **90** can then be examined. For example, it may be preferred to perform a removability check to ensure that the gripper line **90** can be freely moved back and forth within the closed clip before proceeding with subsequent deployment steps, though the gripper line may not be completely removed at this point.

After the gripper line cap **370** has been removed, the lockout **323** may be removed to provide access to the lock line cap **390**, as shown in FIG. **53**. From this configuration, an operator may remove the lock line cap **390** to gain access to the lock line **92**. An operator can remove the lock line **92** from the delivery device **300** by pulling the lock line **92** proximally out of the delivery device **300** (e.g., by pulling on one end and allowing the opposite end to follow through the delivery device **300**).

FIG. **54** illustrates the deployment handle **314** after the lock line cap **390** has been removed. From this configuration, an operator can actuate the actuator handle **351** (e.g., to decouple the implantable device **14** from the delivery catheter **302**). As illustrated, the actuator handle **351** can have one or more indented portions **327** that prevent the actuator handle **351** from being rotated before the gripper line cap **370** and/or lock line cap **390** have been removed. For example, the indented portions **327** can be configured such that the gripper line cap **370** and/or lock line cap **390** fit or partially fit within the indented portions **327**, preventing the actuator handle **351** from rotating past the gripper line cap **370** and/or lock line cap **390** until the gripper line cap **370** and/or lock line cap **390** have been removed. After disen-

gagement of the implantable device **14**, an operator may remove the gripper line **90** by pulling the gripper line proximally from the deployment handle **314** (e.g., as with removal of the lock line **92**).

FIG. **55** illustrates another embodiment of a deployment handle **514** configured to provide staged deployment of an attached implantable device. As shown, the deployment handle **514** can include a telescopic cap **529** configured to slidably move along an actuator knob **505**. For example, upon determining that the attached implantable device has a suitable grasp of targeted tissue, an operator can slide or otherwise position the telescopic cap **529** from a first (e.g., proximal) position at least partially preventing access to the housing lid (not shown), lockout **523**, and other components of the deployment handle **514** into a second (e.g., distal) position providing access to the housing lid, lockout **523**, and other components of the deployment handle **514**.

An example of the telescopic cap **529** in the second position is shown in FIG. **56**. The telescopic cap **529** can be held in a distal position by one or more cap tabs **533** (e.g., providing a snap-fit function), as shown. In other embodiments, a deployment handle can include one or more stops, detents, clips, catches, or other fastening structures for keeping the telescopic cap in a proximal and/or distal position. In other embodiments, a telescopic cap can include a threaded inner surface and can be positioned on threads, such that translation of the telescopic cap results from rotating the telescopic cap upon the threads.

From the configuration shown in FIG. **56**, an operator can remove a gripper line cap **570** to expose a gripper line. An operator may then optionally perform a gripper line removability check by ensuring the gripper line is moveable, though an operator may leave the gripper line in position until subsequent deployment steps (e.g., as a backup in case further manipulation of the gripper line is desired). As shown, the deployment handle **514** can include a lockout **523** (shown as transparent in this view) positioned so as to prevent an operator from gaining access to a lock line cap **590** prior to removing the gripper line cap **570**.

FIGS. **57-58** illustrate separate views of the deployment handle **514** after the gripper line cap **570** has been removed. As shown in FIG. **58**, the lockout **523** can be configured so as to be held in place by a lockout tab **531**. From this configuration, an operator can press the lockout tab **531** to disengage the lockout **523** from the deployment handle **514**. In the illustrated embodiment, the step of removing the lockout **523** can ensure that the attached implantable device is properly positioned in a locked configuration.

For example, FIG. **59** illustrates the deployment handle **514** with the lockout **523** removed. As shown, a lock tab **592** can be positioned through a lock slot **594**, placing the attached implantable device in an unlocked configuration. In this embodiment, because the lock slot **594** is positioned adjacent to the lockout tab **531** (e.g., when the lockout **523** is in the position shown in FIG. **58**), depression of the lockout tab **531** can move the lock tab **592** inwards, allowing it to move distally through the lock slot **594** and into a locked configuration. From this configuration, the lock line cap **590**, actuator handle **551**, and/or other components may be manipulated to further the staged deployment process as described above.

One or more embodiments of the present disclosure can include a deployment handle configured to provide staged deployment of an implantable device from a delivery device. In some embodiments, a deployment handle can include a lock cap removably attached to a housing lid and configured to prevent access to an actuator handle prior to removal of the lock cap. In some embodiments, a lock cap can be configured to engage with a lock tab (such as lock tab **392** described above) upon removal of the lock cap so as to allow a lock line assembly attached to the lock tab to move from an unlocked position toward a locked position, thereby ensuring that an attached implantable device is locked prior to being decoupled via actuation of the actuation handle.

Some embodiments may include an inner cap configured to function as a lock cap (such as inner cap **319** shown in FIGS. **50-51**), and some embodiments may include a lockout configured to function as a lock cap (such as lockout **523** shown in FIGS. **55-58**).

H. Handle Configuration and Operation

FIGS. **60**, **61**A, and **61**B illustrate additional components that may be associated with a delivery device **300**. As shown, the delivery device **300** can be associated with a sleeve housing **700** and/or a outer catheter housing **800**. FIG. **61**A illustrates delivery device **300** coupled to the sleeve housing **700** and outer catheter housing **800** as part of a medical device delivery system **600**. In the illustrated embodiment, the delivery device **300** can be partially housed within the sleeve housing **700** to form a delivery handle. As shown, the sleeve housing **700** can include a sleeve **702** that extends distally from the sleeve housing **700**. The sleeve **702** can be formed with a lumen for receiving the delivery catheter **302** (not visible in FIG. **61**A) as the delivery catheter **302** extends from the delivery device **300** distally to the sleeve **702**. As illustrated, the outer catheter housing **800** can include a outer catheter **802** that extends distally from the outer catheter housing **800**. The outer catheter **802** can be formed with a lumen for receiving the sleeve **702** and/or delivery catheter **302** as the sleeve **702** extends distally from the sleeve housing **700** to the outer catheter housing **800** and/or as the delivery catheter **302** extends distally from the delivery device **300** to the outer catheter housing **800**.

In some embodiments, the outer catheter **802** and/or sleeve **702** can be configured to be guidable. For example, in some embodiments, the outer catheter **802** can be configured to be steerable upon the actuation of steering knob **804** and/or the sleeve **702** can be configured to be steerable upon the actuation of one or more steering knobs **704**. Examples of steering systems, including guidable catheters, sleeves, steering knobs, associated handle controls, and other related components are provided in U.S. Pat. No. 7,666,204, incorporated herein by reference in its entirety. Such a guidable catheter may be referred to herein as a "steerable guide catheter," "guide catheter," "steerable catheter," or "guidable catheter," and such a guidable sleeve may be referred to herein as a "steerable sleeve," "guide sleeve," "guidable sleeve," or "steerable guide sleeve."

As shown, the sleeve housing **700** may include means for securing the sleeve housing to a stabilizer, frame, table, bench, or other structure. Some embodiments include a sleeve housing tab **720** and/or chamfer **724** enabling the sleeve housing **700** to be secured to a stabilizer system. The sleeve housing tab **720** can configured to engage with corresponding receiving means (e.g., a receiving slot) in a stabilizer system, preferably allowing the sleeve housing **700** to be translatable upon the stabilizer system without uncoupling of the sleeve housing tab **720** from the corresponding receiving means. Similarly, the chamfer **724** can be configured to fit within a corresponding receiving portion of a stabilizer system (e.g., a support arm of the stabilizer system sized and shaped to receive the chamfer **724**). In some embodiments, the chamfer **724** can be configured to enable a form fit or friction fit of the sleeve housing **700** into the corresponding receiving portion of the stabilizer system.

Additionally, or alternatively, the sleeve housing **700** can include one or more other linkage means, such as clips, hooks, clasps, etc. configured for securing the medical device delivery system **600** or portions thereof to a stabilizer system or other support structure. FIG. **61**B illustrates an embodiment having a grooved portion **726** in the chamfer **724**. The grooved portion **726** can be configured to match a corresponding structure of a stabilizer system, such as a pin, rail, bar, or the like, thereby enabling and/or enhancing securement of the sleeve housing **700** to the stabilizer system. Examples of a stabilizer system to which embodiments of medical device delivery systems can be attached may be found in U.S. patent application Ser. No. 14/879,674, filed Oct. 9, 2015.

FIGS. **62-63** illustrate a delivery device **300** partially housed within a sleeve housing **700**, with a portion of the sleeve housing **700** shown in cutaway view for clarity. As illustrated, the shell **306** of the delivery device **300** can extend into the sleeve housing **700**. The sleeve housing **700** can be configured to secure the delivery device **300** while allowing the position of the delivery device **300** to be adjusted relative to the sleeve housing **700**. For example, the sleeve housing **700** can include a lock, such as spring clamp **706** positioned around the delivery device **300** when the delivery device **300** is inserted and/or housed within the sleeve housing **700**. The spring clamp **706** can be configured to have a diameter that is smaller when the spring clamp **706** is in a relaxed configuration than when the spring clamp **706** is in a stressed configuration (e.g., the spring clamp **706** can include one or more torsion springs).

For example, when the spring clamp **706** is in a relaxed configuration, the spring clamp **706** can tighten against the delivery device **300** to secure the delivery device **300** in position relative to the sleeve housing **700** (e.g., to prevent translation and/or rotation of the delivery device **300**). When the spring clamp **706** is placed in a stressed configuration, the diameter of the spring clamp **706** can enlarge to allow the delivery device **300** to freely translate and/or rotate relative to the sleeve housing **700**. For example, the spring clamp **706** can be formed with one or more arms extending radially outward from the spring clamp **706**. Repositioning of the one or more arms (e.g., relative to each other and/or relative to the spring clamp **706**) can move the spring clamp **706** toward a stressed (i.e., unlocked) configuration or toward a relaxed (i.e., locked) configuration.

Other embodiments may include one or more other mechanisms for adjustably securing a delivery device to a sleeve housing. For example, some embodiments may include a lock configured as a set screw for adjustably securing a delivery device to a sleeve housing; some embodiments may include one or more locks configured as clips, clasps, flanges, tabs, brackets, latches, bolts, or other adjustable securing means; and some embodiments may include one or more locks configured as magnetic components, hook and loop fasteners (e.g., Velcro®), spring button locks, and/or a pin and hole assembly for adjustably securing a delivery device and a sleeve housing.

As illustrated, the sleeve housing **700** can include a handle **708**. The handle **708** can be engageable with the spring clamp **706** such that actuation of the handle **708** adjusts the spring clamp **706** (e.g., toward a relaxed configuration or toward a stressed configuration). The handle **708** can be coupled to a lock actuator. As shown in the illustrated embodiment, the lock actuator can be configured as a yoke **710**. The yoke **710** can be configured so as to engage with the spring clamp **706** upon actuation (e.g., depression) of the handle **708**. For example, in some embodiments, depression of the handle **708** can move the yoke **710** into contact with one or more arms of the spring clamp **706**. Further movement of the yoke **710** can adjust the position of the one or more arms of the spring clamp **706**, thereby positioning the spring clamp **706** toward a stressed configuration or toward a relaxed configuration. For example, depression of the handle **708** can move the spring clamp **706** toward a stressed configuration, providing a larger diameter for the shell **306** of the delivery device **300** to be translated and/or rotated within the spring clamp **706**.

As shown, the yoke **710** can have a furcated shape. The yoke **710** can be configured to fit partially around the spring clamp **706** and/or shell **306**. For example, the yoke **710** can be configured in size and shape so as to be capable of engaging with one or more arms of the spring clamp **706** without contacting the shell **306** and/or other portions of the spring clamp **706**.

As illustrated, the sleeve housing **700** can also include a handle spring **712**. The handle spring **712** can be configured to apply a force directing the handle **708** and/or yoke **710** towards a default position (e.g., a position associated with a locked configuration). For example, the handle spring **712** can be coupled to the yoke **710** at a first end and to the sleeve housing **700** at a second end such that tension in the handle spring **712** can pull the yoke **710** away from the spring clamp **706** in the absence of an overriding force. Other embodiments may additionally or alternatively include one or more coil springs and/or leaf springs, such as a coil or leaf spring configured to push or pull a yoke away from a spring clamp or a coil or leaf spring configured to push or pull a handle toward a default position (e.g., a position associated with a locked configuration).

In some embodiments, the handle **708** can be configured to be selectively held in a depressed position (e.g., as opposed to automatically reverting back to a default position upon removal of the depressing force). For example, the sleeve housing **700** can include an override configured to engage with the handle **708** to prevent movement of the handle **708**. The override and/or handle can be configured to prevent movement of the handle toward the default position, toward the depressed position, or in either direction upon engaging the override against the handle **708**. For example, the override can be configured as a pin, latch, clasp, stop, or other structure that extends out of or partially out of the sleeve housing **700**. In some embodiments, the override can be configured to maintain the handle in a depressed position when engaged with the handle.

The override can be inserted into or further into the sleeve housing **700** so as to engage with the handle **708** and limit movement of the handle **708**. For example, the override and or handle **708** may be configured such that, after the handle **708** has been moved to a depressed position (e.g., to unlock the delivery device **300**), the override may be engaged so as to prevent the handle **708** from automatically returning to the default position. In this configuration, the delivery device can remain free to translate and/or rotate relative to the sleeve housing **700** without the need for constant pressure against the handle **708**.

As illustrated, the sleeve housing **700** can also include a lock button **714** configured to engage with the spring clamp **706** to move the spring clamp **706** from the locked configuration toward the unlocked configuration. The lock button **714** can be positioned at a location on the sleeve housing **700** opposite the handle **708**. For example, as illustrated, the lock button **714** can be positioned on an upper portion **716** of the sleeve housing **700** and/or above the delivery device **300**. The lock button **714** may be configured to be engageable

with the spring clamp **706** such that actuation of the lock button **714** adjusts the spring clamp **706** (e.g., toward a relaxed configuration or toward a stressed configuration). For example, depression of the lock button **714** can move the spring clamp **706** toward a stressed configuration, providing a larger diameter for the shell **306** of the delivery device **300** to be translated and/or rotated within the spring clamp **706**.

In some embodiments, the lock button **714** can be configured so as to maintain position after being actuated. For example, some embodiments may include a lock button that maintains engagement with a spring lock or other locking means after being actuated (e.g., after being depressed). In other embodiments, a lock button may return to a default position upon removal of an actuating force. For example, in some embodiments, a lock button may be allowed to return to a locked configuration upon removal of an actuating force.

In some embodiments, a delivery device can include a clutch case disposed on a portion of the delivery device positioned within a sleeve housing (e.g., disposed on a shell of the delivery device). In such embodiments, the sleeve housing may include a binding plate configured to extend through the sleeve housing. The binding plate can be adjustably positioned to engage with the clutch case to prevent translation of the delivery device. For example, the binding plate can be configured to fall into position within and/or against the clutch case when the delivery device is positioned so as to bring the clutch case or receiving portion thereof below the binding plate, thereby preventing further translation of the delivery device.

As illustrated, the sleeve housing **700** and/or delivery device **300** can be configured to operate together to allow translation and/or rotation of the delivery device **300** relative to the sleeve housing **700**. One or more embodiments may be configured to beneficially allow one-handed operation of the delivery device **300**. For example, the handle **708** can be located in a position relative to the delivery device **300** that allows simultaneous manipulation of the delivery device **300** and control of the handle **708**. In some embodiments, the handle **708** or portion thereof can be positioned below the translation knob **304** of the delivery device **300** and/or can be positioned from a lower portion **718** of the sleeve housing.

As illustrated, the sleeve housing **700** can include a grip section **722** extending transversely from a longitudinal axis of the sleeve housing **700** and/or delivery device **300**. The handle **708** can be disposed on a proximal side of the grip section **722**. From such a configuration, an operator may depress the handle **708** using the palm of his/her hand in order to unlock the delivery device **300** from the sleeve housing **700**. With his/her hand in this position (e.g., while still maintaining force against the handle **708**), the operator can freely manipulate the delivery device **300** (e.g., by manipulating the translation knob **304**) using the thumb and/or fingers of his/her same hand.

The illustrated embodiment can also allow one-handed operation from the upper portion of the sleeve housing **700**. For example, an operator may position his/her hand above the sleeve housing **700**. From this position, the operator may actuate the lock button **714** and/or grasp the translation knob **304**. For example, an operator may use his/her palm, a thumb and/or other fingers to actuate the lock button **714** while using the palm, thumb, and/or other fingers of the same hand to manipulate the delivery device **300** (e.g., by manipulating the translation knob **304** of the delivery device **300**). As shown, the translation knob **304** may be positioned on a portion of the delivery device **300** exterior to the sleeve housing **700** so as to allow a user to manipulate the translation knob **304**.

Some embodiments may include different configurations of handles and/or lock buttons. For example, some embodiments may omit lock buttons or handles, some embodiments may include two or more lock buttons (e.g., by replacing the handle **708** of the illustrated embodiment with a lock button), and some embodiments may include two or more handles (e.g., by replacing the lock button **714** of the illustrated embodiment with a handle). Some embodiments may include one or more lock buttons and/or handles disposed at different locations on a sleeve housing, such as one or more lock buttons and/or handles extending from a side portion of the sleeve housing and/or extending horizontally, vertically, or diagonally.

The one-handed operation made possible by certain embodiments disclosed herein can provide a number of benefits. For example, an operator may manipulate the position of the delivery device **300** relative to the sleeve housing **700** with one hand, freeing the other hand to manipulate and/or actuate other components of the delivery system **600**, such as the deployment handle **314**, outer catheter housing **800**, steering knobs **704**, **804**, fluid management system **308**, and/or collar **310**.

I. Industrial Applicability

It will be appreciated that delivery systems of the present disclosure may include any or all of the components described herein. In addition, delivery systems of the present disclosure may be used to introduce other delivery catheters, interventional catheters, introducers, guiding systems, and/or other devices. Likewise, delivery devices may be used to deliver a variety of types of devices to a target location within the body, including endoscopic staples, heart valves, annuloplasty rings, and/or other medical devices used in angioplasty, atherectomy, stent-delivery, embolic filtration and removal, septal defect repair, tissue approximation and repair, vascular clamping and ligation, electrophysiology mapping or ablation, suturing, aneurysm repair, and/or vascular occlusion, for example.

The embodiments of the present disclosure can be used in a variety of industrial applications. For example, some embodiments include a method of positioning a medical device using a stabilizing system according to the present disclosure, and such systems, devices, and methods can be used in a medical procedure where manipulation and positioning of a medical device is required and/or desired.

In addition, such systems, devices, and methods can be applied in a medical products testing industry or medical products analysis industry. For example, the ability of a medical device to be supported, positioned, reoriented, and/or manipulated can be tested and analyzed using the devices, systems, and methods of the present disclosure. Further, operational and durability limits of a medical device under such uses can be tested and/or analyzed.

In addition, embodiments of the present disclosure can be used in a medical operator training industry. For example, one or more devices, systems, or methods of the present disclosure can be used in a training application allowing a physician, surgeon, doctor, or medical engineer to undergo training by positioning, manipulating, reorienting, and/or repositioning a medical device.

While the foregoing is a complete description of the preferred embodiments, various alternatives, substitutions, additions, modifications, and equivalents are possible without departing from the scope of the invention. For example, in many of the above-described embodiments, the invention

is described in the context of approaching a valve structure from the upstream side, that is, the atrial side in the case of a mitral valve. It should be understood that any of the foregoing embodiments may be utilized in other approaches as well, including from the ventricular or downstream side of the valve, as well as using surgical approaches through a wall of the heart. Moreover, various embodiments may be used in the treatment of a variety of other tissue structures besides heart valves, and will find usefulness in a variety of tissue approximation, attachment, closure, clamping and ligation applications, some endovascular, some endoscopic, and some open surgical.

The terms "approximately," "about," and "substantially" as used herein represent an amount or condition close to the stated amount or condition that still performs a desired function or achieves a desired result. For example, the terms "approximately," "about," and "substantially" may refer to an amount that deviates by less than 10%, or by less than 5%, or by less than 1%, or by less than 0.1%, or by less than 0.01% from a stated amount or condition.

In addition, unless expressly described otherwise, all stated amounts (e.g., angle measurements, dimension measurements, etc.) are to be interpreted as being "approximately," "about," and/or "substantially" the stated amount, regardless of whether the terms "approximately," "about," and/or "substantially" are expressly stated in relation to the stated amount(s).

Further, elements described in relation to any embodiment depicted and/or described herein may be combinable with elements described in relation to any other embodiment depicted and/or described herein. For example, any element described in relation to an embodiment depicted in FIGS. **4** through **31** may be combinable with an embodiment described depicted in FIGS. **32** through **63**.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

The invention claimed is:

1. A medical delivery system, comprising:

a housing;

a delivery device disposed at least partially within the housing;

a lock configured to releasably secure the delivery device relative to the housing when in a locked configuration, and to allow translation of the delivery device within the housing when in an unlocked configuration, the lock disposed on a portion of the delivery device and selectively contacts an outer surface of the portion of the delivery device to selectively lock both translation and rotation of the portion, the lock is configured as a spring clamp, the spring clamp having a diameter when in a relaxed configuration that is smaller than a diameter when in a stressed configuration;

a lock actuator configured to engage with the lock to move the lock from the locked configuration toward the unlocked configuration; and

a handle coupled to the lock actuator, the handle being configured to move the lock actuator to engage with the lock upon the handle being moved from a default position toward a depressed position;

a sleeve having a proximal end coupled to the housing; and

a catheter having a proximal end coupled to the delivery device, the catheter extending distally from the delivery device through a lumen of the sleeve;

wherein depression of the handle allows the delivery device to be translated within the housing so as to translate the catheter within the sleeve.

2. The system of claim **1**, wherein the housing includes a grip section extending transversely from a longitudinal axis of the housing, the handle being disposed at the grip section on a proximal side of the grip section.

3. The system of claim **1**, wherein the delivery device includes a translation knob disposed on a section of the delivery device external to the housing, the translation knob including a gripping surface.

4. The system of claim **1**, wherein the lock actuator is configured as a yoke having a furcated shape, and is configured to engage with one or more arms extending radially outward from the spring clamp in order to move the spring clamp toward the stressed configuration.

5. The system of claim **1**, further comprising a handle spring configured to apply a force directing the handle towards the default position.

6. The system of claim **5**, wherein the handle spring is coupled to the lock actuator at a first end and to the housing at a second end such that tension in the handle spring can pull the lock actuator away from the lock.

7. The system of claim **1**, further comprising an override configured to engage with the handle to prevent movement of the handle.

8. The system of claim **7**, wherein the override is configured as a pin extending through the housing to engage with the handle.

9. The system of claim **7**, wherein the override is configured to maintain the handle in the locked configuration when engaged with the handle.

10. The system of claim **1**, further comprising a lock button configured to engage with the lock upon being moved from a default position toward a depressed position so as to move the lock from the locked configuration toward the unlocked configuration.

11. The system of claim **10**, wherein the lock button is disposed on a portion of the housing opposite the handle.

12. The system of claim **1**, further comprising a binding plate configured to engage with a clutch case of the delivery device to prevent translation of the delivery device within the housing.

13. A medical delivery system, comprising:

a sleeve housing;

an outer catheter housing;

an outer catheter having a proximal end coupled to the outer catheter housing;

a sleeve having a proximal end coupled to the sleeve housing, the sleeve extending distally from the sleeve housing through a lumen of the outer catheter;

a delivery device disposed at least partially within the sleeve housing;

a delivery catheter having a proximal end coupled to the delivery device, the delivery catheter extending distally from the delivery device through a lumen of the sleeve;

a lock configured to releasably secure the delivery device relative to the sleeve housing when in a locked configuration, and to allow translation of the delivery device within the sleeve housing when in an unlocked configuration, the lock encircling a portion of the delivery device and selectively contacts an outer surface of the portion of the delivery device to selectively lock translation and rotation of the portion, the lock is

configured as a spring clamp, the spring clamp having a diameter when in a relaxed configuration that is smaller than a diameter when in a stressed configuration;

a lock actuator configured to engage with the lock to move the lock from the locked configuration toward the unlocked configuration;

a handle coupled to the lock actuator, the handle being configured to move the lock actuator to engage with the lock upon the handle being moved from a default position toward a depressed position; and

an implantable device coupled to a distal end of the delivery catheter and configured to be implantable at a target area;

wherein depression of the handle allows the delivery device to be translated within the housing so as to translate the guide catheter within the sleeve and the outer catheter, enabling the implantable device to be translated relative to a target area.

14. The delivery system of claim **13**, wherein the housing includes a grip section extending transversely from a longitudinal axis of the housing, the handle being disposed at the grip section on a proximal side of the grip section.

15. The delivery system of claim **13**, wherein the delivery device includes a translation knob disposed on a section of the delivery device external to the housing, the translation knob including a gripping surface.

16. The delivery system of claim **13**, further comprising a lock button configured to engage with the lock upon being moved from a default position toward a depressed position so as to move the lock from the locked configuration toward the unlocked configuration.

17. A method of positioning a delivery catheter at a target area, the method comprising:

positioning a distal end of a sleeve at a target area, the sleeve having a proximal end coupled to a delivery assembly, the delivery assembly including:

a housing coupled to the sleeve;

a delivery device disposed at least partially within the housing;

a lock configured to releasably secure the delivery device relative to the housing when in a locked configuration, and to allow translation of the delivery device within the housing when in an unlocked configuration, the lock disposed on a portion of the delivery device and selectively contacts an outer surface of the portion of the delivery device to selectively lock translation and rotation of the portion, the lock is configured as a spring clamp, the spring clamp having a diameter when in a relaxed configuration that is smaller than a diameter when in a stressed configuration;

a lock actuator configured to engage with the lock to move the lock from the locked configuration toward the unlocked configuration; and

a handle coupled to the lock actuator, the handle being configured to move the lock actuator to engage with the lock upon the handle being moved from a default position toward a depressed position;

depressing the handle to allow the delivery device to be translated within the housing; and

translating the delivery device within the housing so as to translate the catheter within the sleeve.

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